SMITH & NEPHEW RICHARDS

GENESIS®

TOTAL KNEE SYSTEM

REVISION

POSTERIOR REFERENCING INSTRUMENTATION

SURGICAL TECHNIQUE

CONTENTS

INTRODUCTION

As a revision system, GENESIS recognizes that quality bone stock is a precious commodity... and bone resection to match component size may not be an option. With the GENESIS Total Knee System, each area of the knee and each facet of the procedure may be augmented to produce a better implant. Component stability generally is achieved even in patients with bony deformities because the GENESIS Total Knee System's modularity allows the surgeon to custom assemble a knee prosthesis that suits the needs of each patient.

Patients indicated for a total knee replacement generally have a deficient anterior cruciate ligament. Many patients have additional ligamentous insufficiency, usually the posterior cruciate ligament and/or the collateral ligaments. Historically, various methods have been employed to address the stability of the knee joint including prostheses with greater constraint between the articulating surfaces of the femur and tibia and hinged prostheses. A large variety of implants creates an inventory that can become excessive. A solution is provided by using a prosthesis with modular inserts for the components. Modularity allows a variety of solutions without the inventory burden associated with nonmodular, "fixed" prostheses.

The need for modularity is extensive. Frequently, intraoperative decisions must be made regarding component dimensions, soft tissue balance, or ligamentous stability warranting changes in the choice of the femoral component. Nonmodular systems require a separate prosthesis, often requiring different bone cuts and different instruments. To address the problem more efficiently, a prosthetic knee system should feature components that can be modified through the addition of "conversion modules" to optimize surgical flexibility. The change from a Cruciate-Retaining to a Revision component can be made intraoperatively by the addition of a conversion module to the standard femoral component.

Alignment is critical to the outcome of a total knee replacement. Instrumentation for total knees has evolved over time. To ensure that proper limb alignment is restored, a combination of intramedullary alignment devices with extramedullary alignment check rods is necessary. These steps increase the probability for a successful clinical outcome.

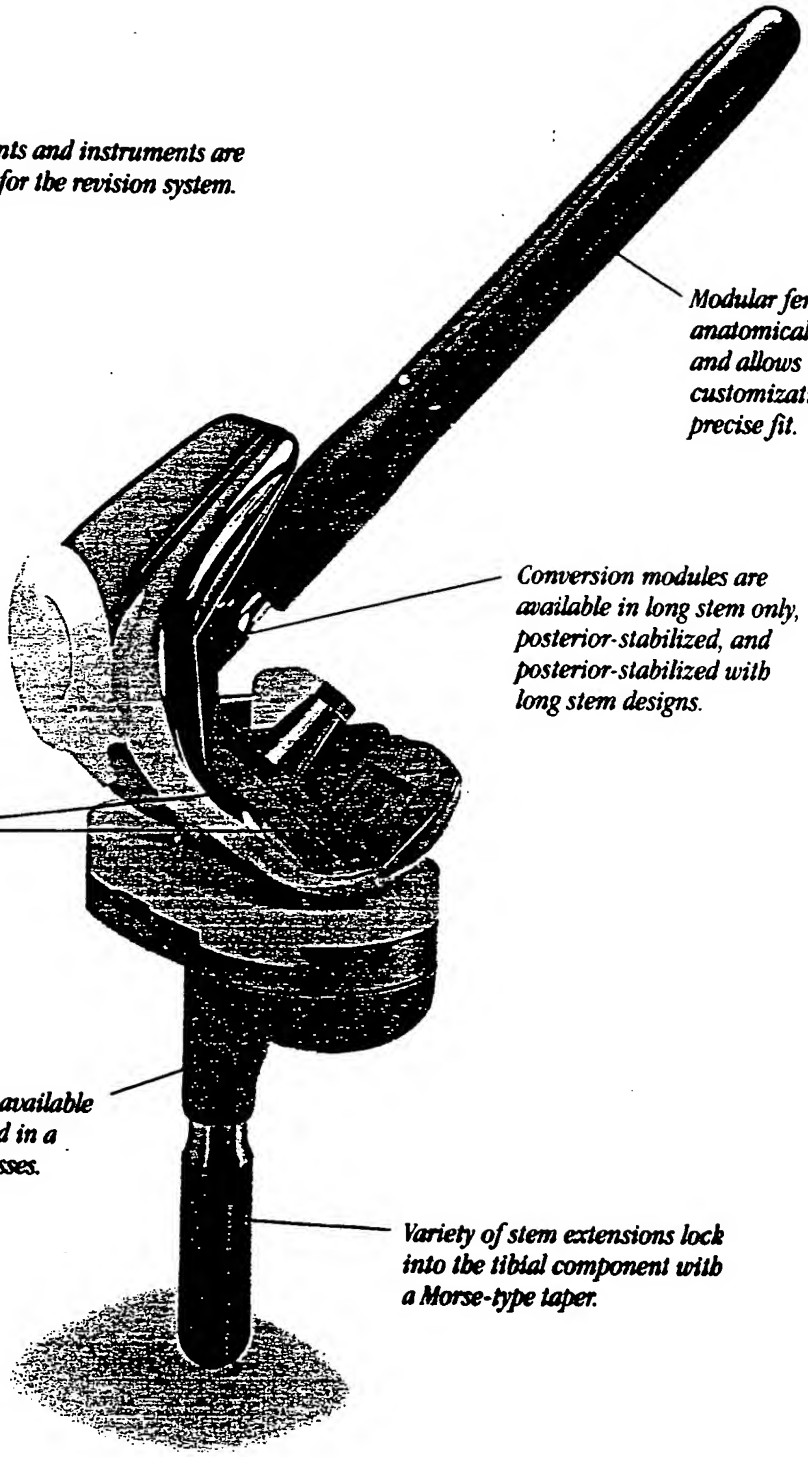
The management of bone defects can be a difficult problem in total knee replacement. A variety of methods can be employed, including filling the defects with cement which can be reinforced with wire mesh or bone screws, altering the level of bone resection to eliminate the defect, the use of metal wedges or custom components, and the use of bone grafts.

Metal wedges provide more surgical flexibility than custom implants and can avoid some of the problems associated with other options for management of bone defects, such as cement shrinkage or laminations, limited donor bone, or failure of graft incorporation. Metal wedge studies have shown that the levels of force transmission are uniform and approach that of a custom implant.

Preoperative planning provides only a limited view of the exact patient conditions for a total knee arthroplasty. In some extreme conditions, intraoperative anatomy reveals a different picture and requires a different treatment. In order to best address this occurrence, a total knee system should be flexible enough to address the unexpected. The GENESIS Total Knee System is designed with the flexibility to deal with unexpected problems. The system incorporates features designed with clinically-verified principles in mind. The modularity of GENESIS allows the surgeon to custom-assemble an implant for each individual patient.

The surgical technique that follows has been developed as a guide to using the GENESIS Revision implants. It will also demonstrate that, for primary or revision procedures, the GENESIS design combines excellent fit with substantial flexibility.

DESIGN FEATURES



Primary implants and instruments are used as a base for the revision system.

Modular femoral stem is anatomically positioned and allows implant customization for a precise fit.

Conversion modules are available in long stem only, posterior-stabilized, and posterior-stabilized with long stem designs.

Wedges can augment the femoral component distally and posteriorly; symmetrically or asymmetrically.

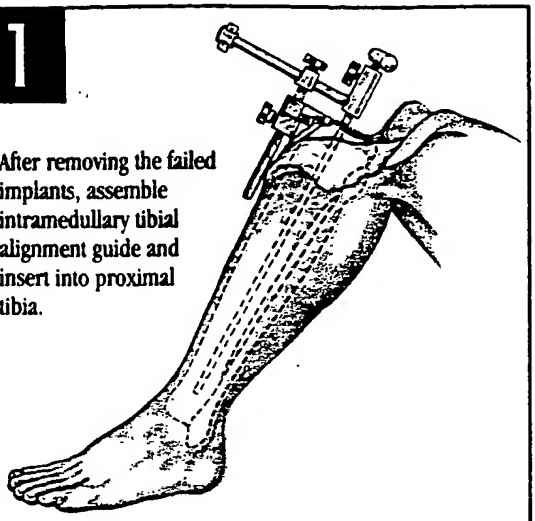
Tibial wedges are available in five designs and in a variety of thicknesses.

Variety of stem extensions lock into the tibial component with a Morse-type taper.

SHORT TECHNIQUE

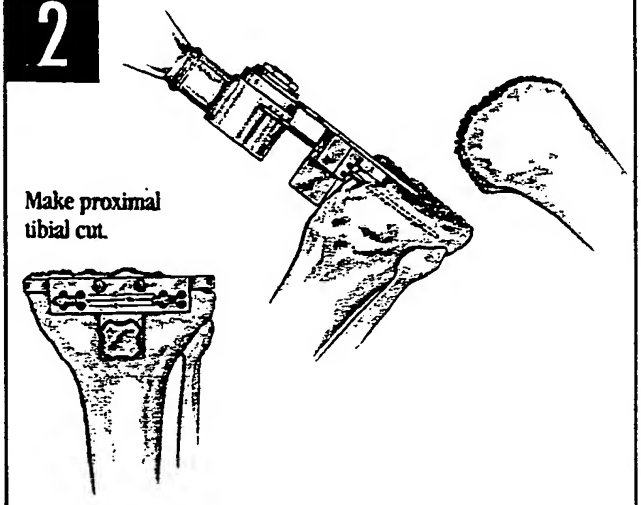
1

After removing the failed implants, assemble intramedullary tibial alignment guide and insert into proximal tibia.



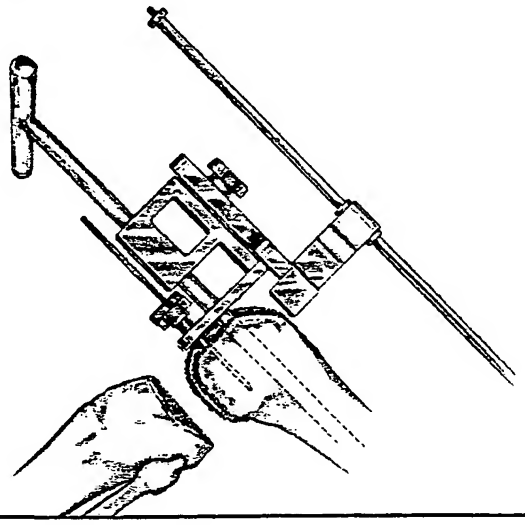
2

Make proximal tibial cut.



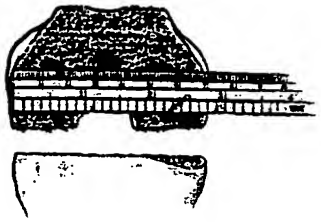
4

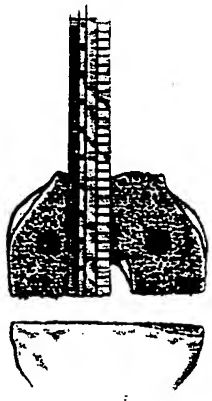
Insert femoral intramedullary alignment guide which has been set at a 7° valgus angle.



6

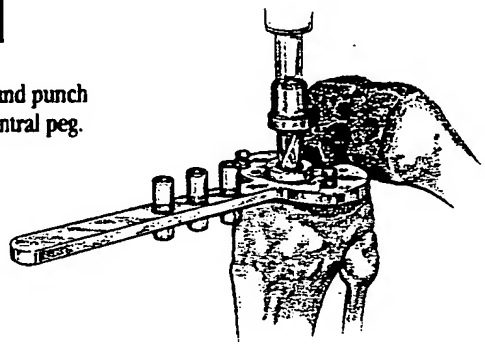
For femoral component sizing, measure A-P and M-L dimensions of distal femur and the flexion and extension gaps. Decide upon femoral component sizing based upon these measurements.

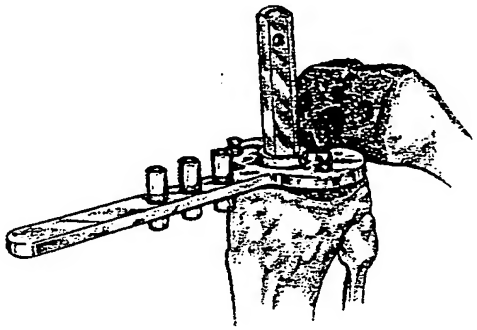




3

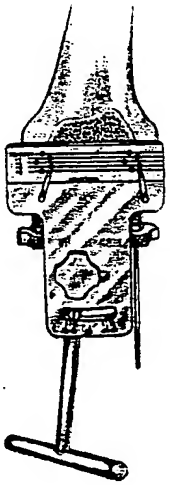
Drill and punch for central peg.

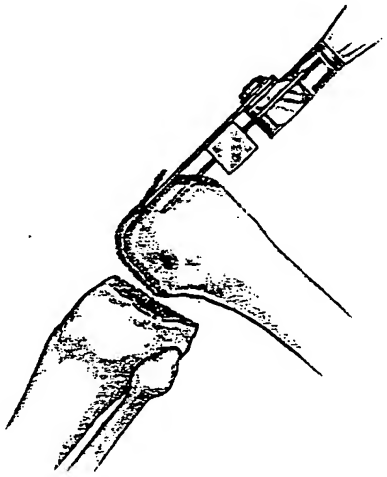


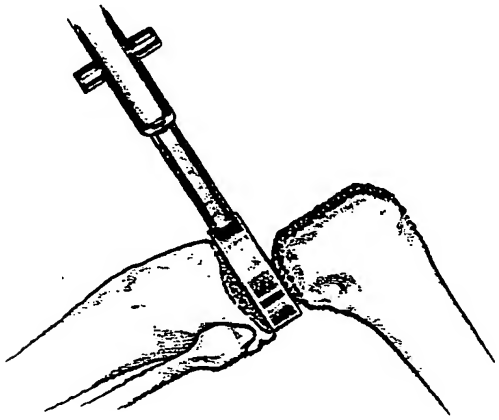


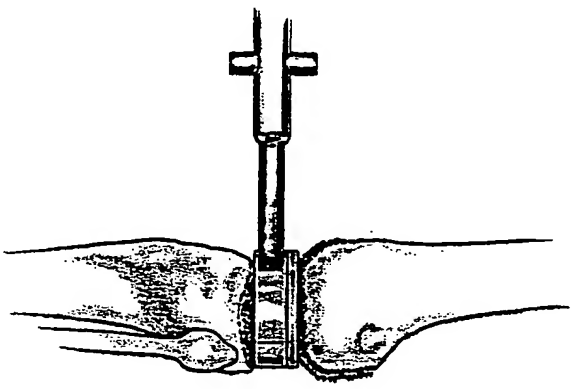
5

Drill holes through the "+6" holes of the distal cutting block. Move distal femoral cutting block forward to remove as little bone as possible. Make distal cut.



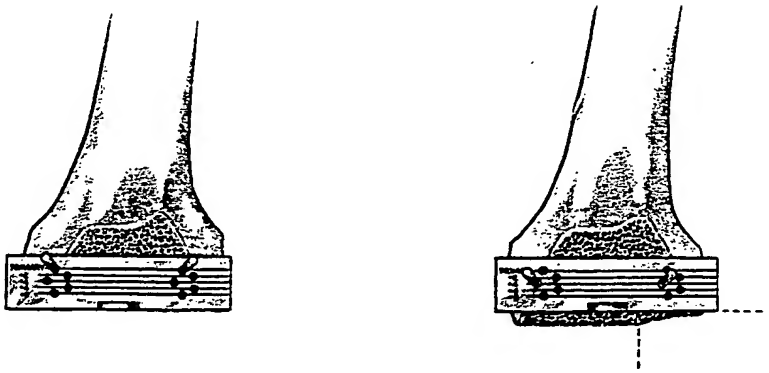






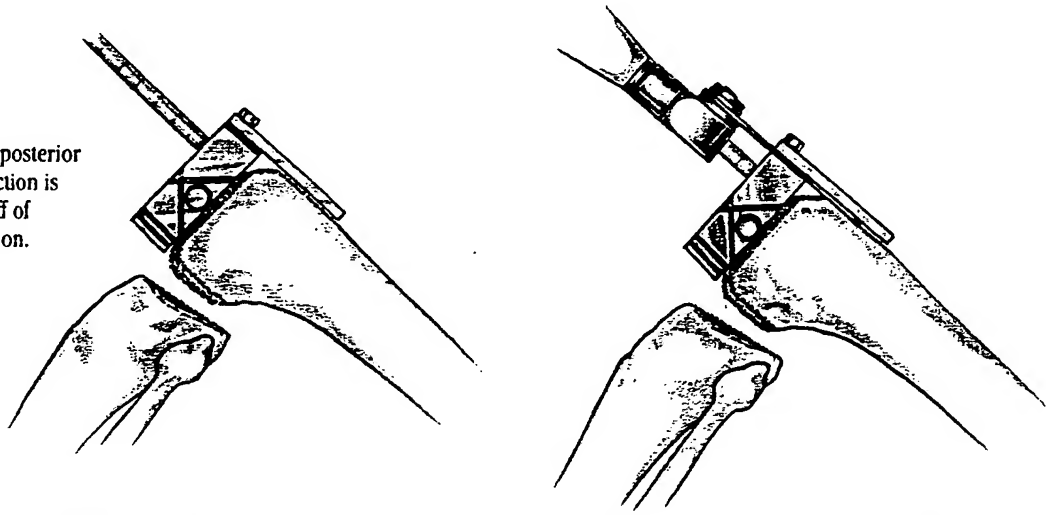
7

Distal femoral wedge resection.



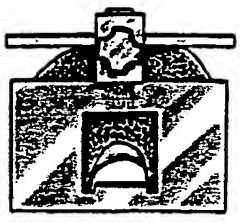
9

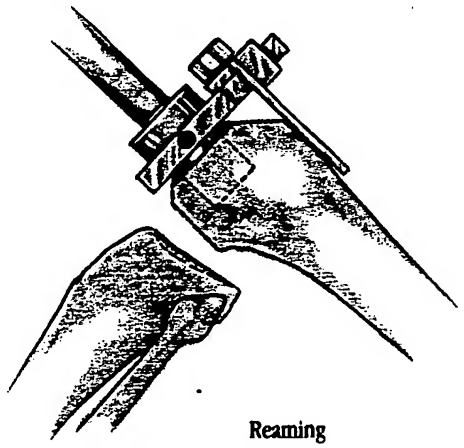
Anterior and posterior femoral resection is referenced off of reamer position.



11

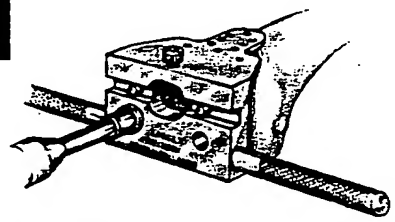
Additional femoral cuts performed when using a posterior-stabilized module.



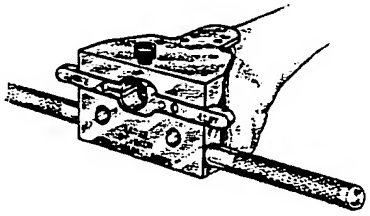


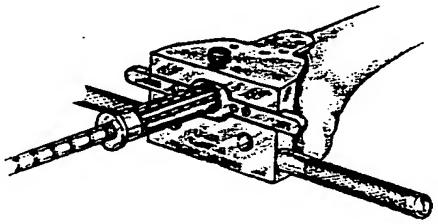
Reaming

8



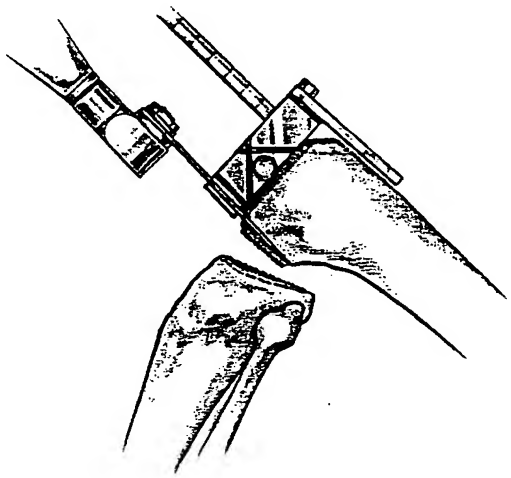
Femoral component alignment and long stem reaming.

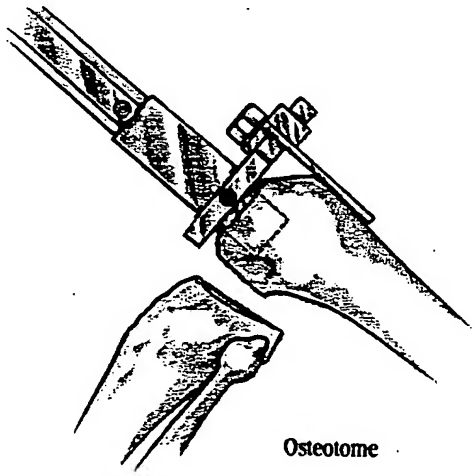




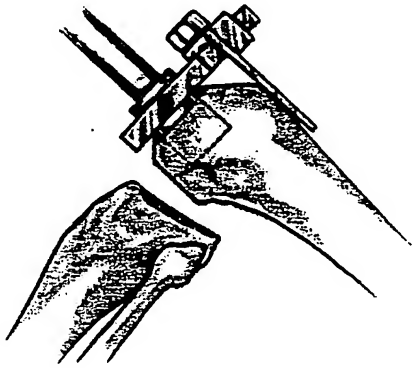
10

Posterior wedge resection.





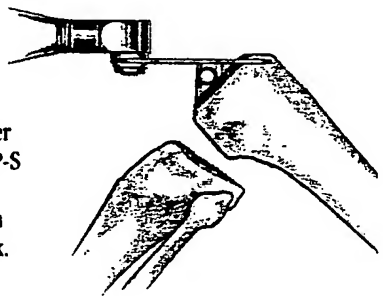
Osteotome



Housing Sizer

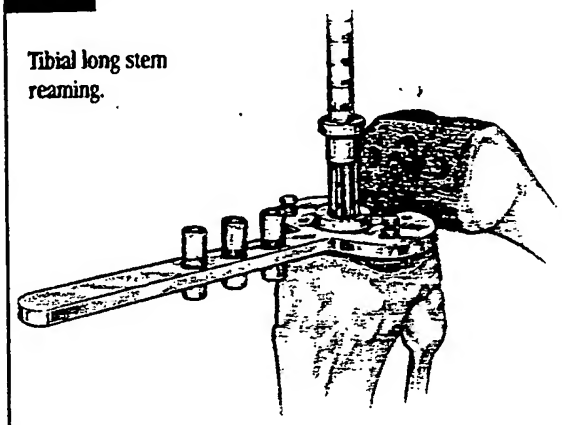
12

Anterior and posterior chamfer resection using P-S chamfer cutting block or revision A-P cutting block.



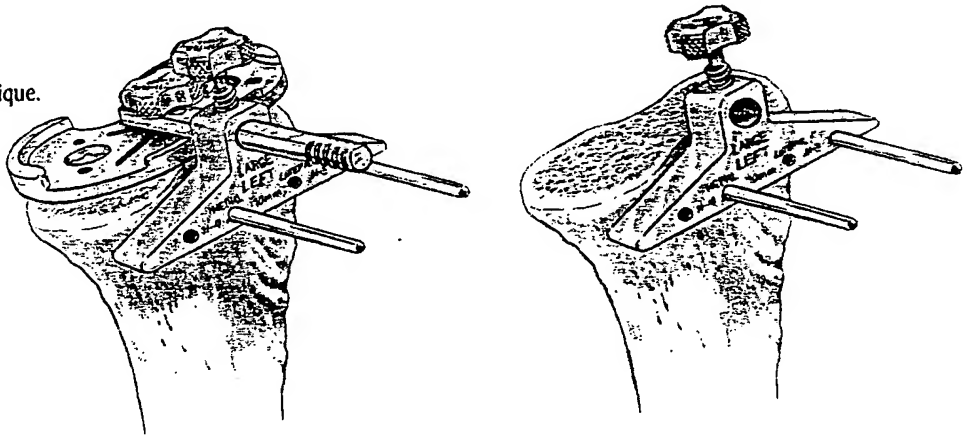
13

Tibial long stem reaming.



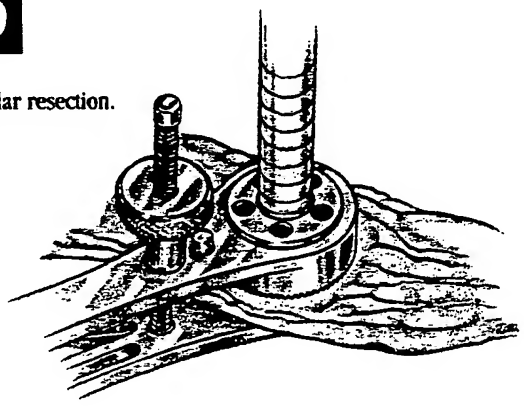
14

Tibial wedge technique.



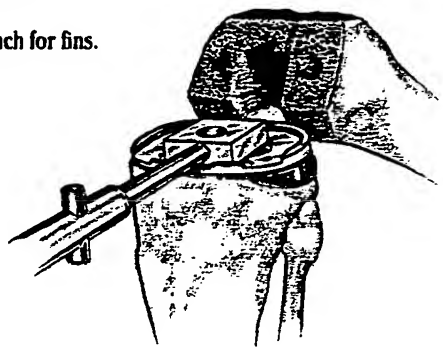
15

Patellar resection.



16

Punch for fins.



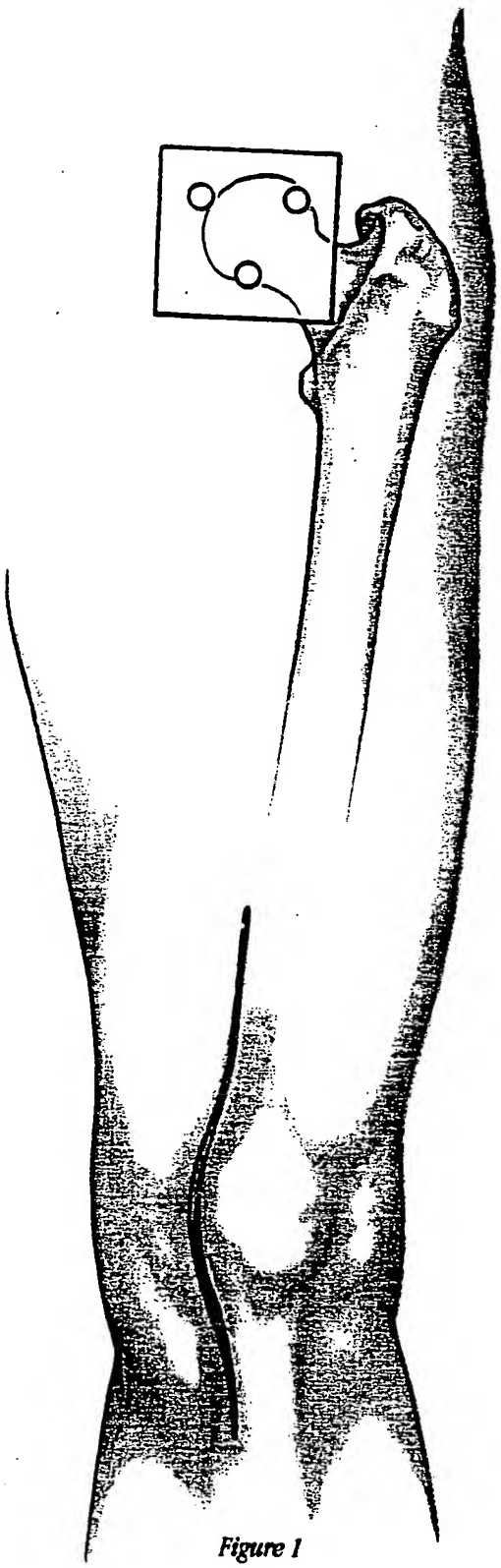
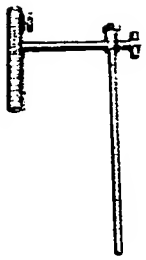


Figure 1

PATIENT PREPARATION

Place a radiographic marker over the femoral head of the patient and confirm its position immediately by an X-ray preoperatively *(Figure 1)*. The marker will allow intraoperative determination of the mechanical axis of the limb. Perform a standard surgical scrub and iodoform forepainting of the extremity with placement of a tourniquet high on the thigh. Use sterile draping of the extremity. Place a nonbulky drape around the foot and ankle so that the bony anatomy can be palpated when using the tibial extramedullary alignment guide.



Tibial Intramedullary Alignment Assembly 11-4599

Tibial Cutting Block
0° – 11-4663
3° – 11-4665

Tibial Cutting Block, Slotted
0° – 11-4664
3° – 11-4666

Assemble the intramedullary alignment rod and 3° posterior sloped cutting guide. **HOWEVER, IF A LONG STEMMED TIBIAL COMPONENT WILL BE UTILIZED, A 0° CUTTING BLOCK MUST BE USED.** Slowly insert the rod into the tibia and advance it distally as far as possible. It should progress to the supramalleolar level being impeded finally by the remnant of epiphyseal scar *(Figure 6)*. The outrigger of the guide should be aligned with the medial third of the tibial tubercle *(Figure 7)*.

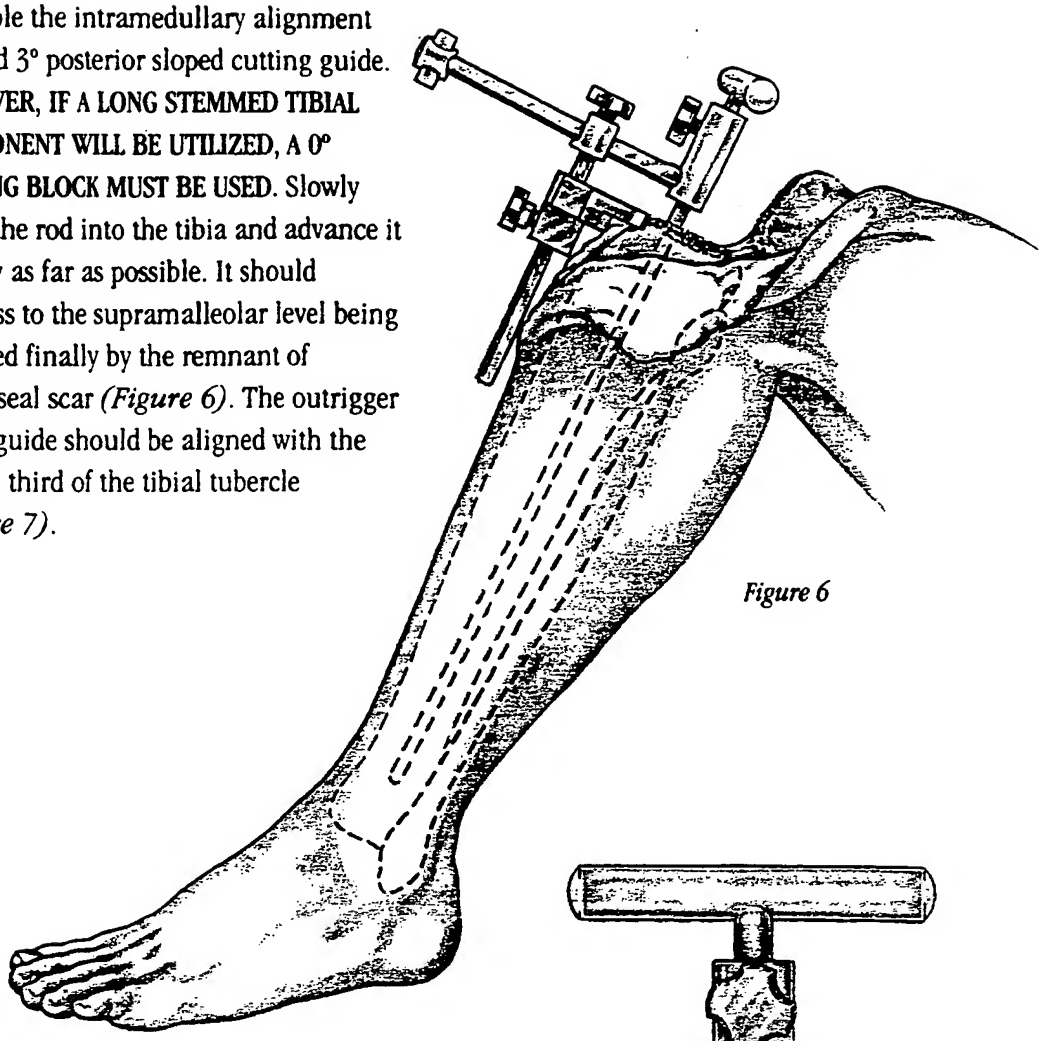


Figure 6

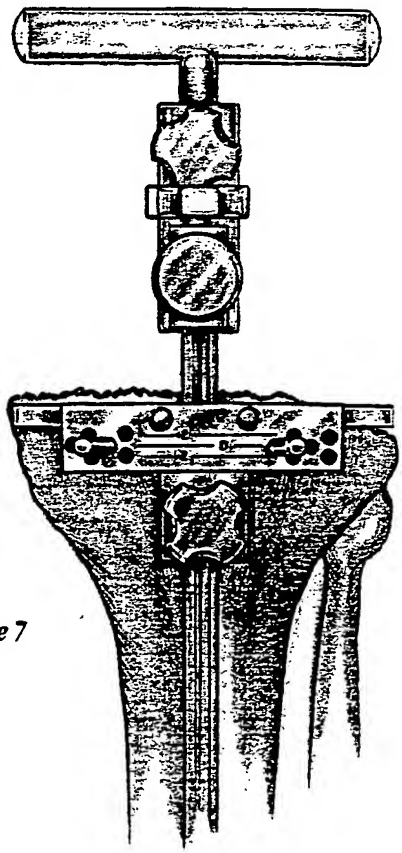


Figure 7

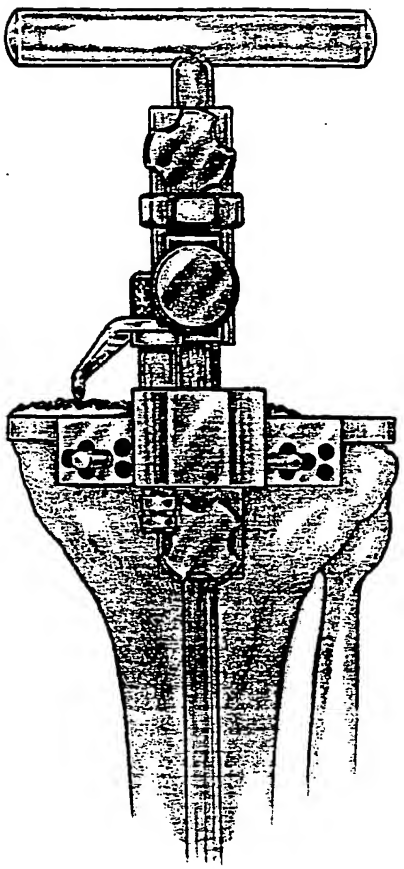


Figure 8

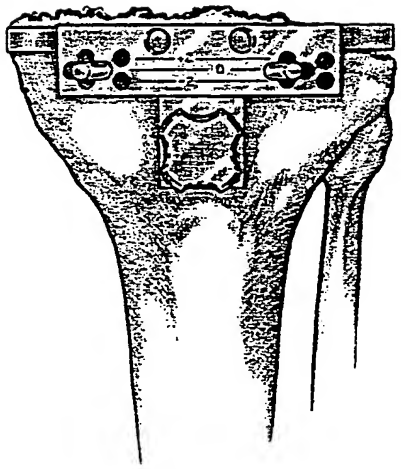
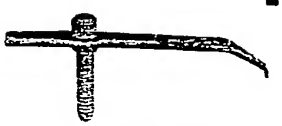


Figure 9

Assess the compartments of the tibia to determine the lowest point on the plateau. In case of bony defects, it may be necessary to adjust the cutting level proximal to or above the level of maximum bone loss and to subsequently graft the defect or use an augmentation wedge. Raise the tibial cutting block to its most proximal position on the tibial rod. Attach the desired proximal tibial stylus and tighten the stylus down by its knurled knob. Five different stylus levels are available: 0, 2, 4, 6, and 8 mm. Using a 0 mm stylus, the level of cut will be even with the end of the stylus gauge. Using a 2 mm stylus, the level of the cut will be 2 mm below the level of the end of the stylus gauge, and so forth. Position the cutting block so that a minimal amount of bone will be resected and then tighten all of the screws on the guide. To correctly position the tibial cutting block, make sure the lateral wing is between the patellar tendon and the tibia. There are two holes in the tibial block on either side of the alignment rod. Insert a ⅛" drill into a hole on each side of the tibial assembly to affix the cutting block to the anterior surface of the tibia *(Figure 8)*. Take care to retract the patellar ligament laterally so that it is not injured by a drill. Remove the intramedullary rod and alignment guide, leaving the tibial cutting block in place against the anterior tibia *(Figure 9)*.



Tibial Stylus
11-4668
11-4671
11-4672
11-4673
11-4674

GENESIS Sawblades
11-4542
11-4549
11-4551
11-4553

Retract the patellar ligament laterally and resect the proximal tibia over the cutting block using a GENESIS sawblade. These blades correctly match the width of our cutting slots and will reduce the amount of play between the cutting slot and the blade *(Figure 10)*. The cutting block and guide are constructed to result in a 3° downward slope (or 0° slope) to the tibial cut, and a 90° cut in the M-L plane. It is usually easier to resect the medial plateau first. If it is difficult to remove the entire tibial surface, it can be split down the middle and removed in sections.

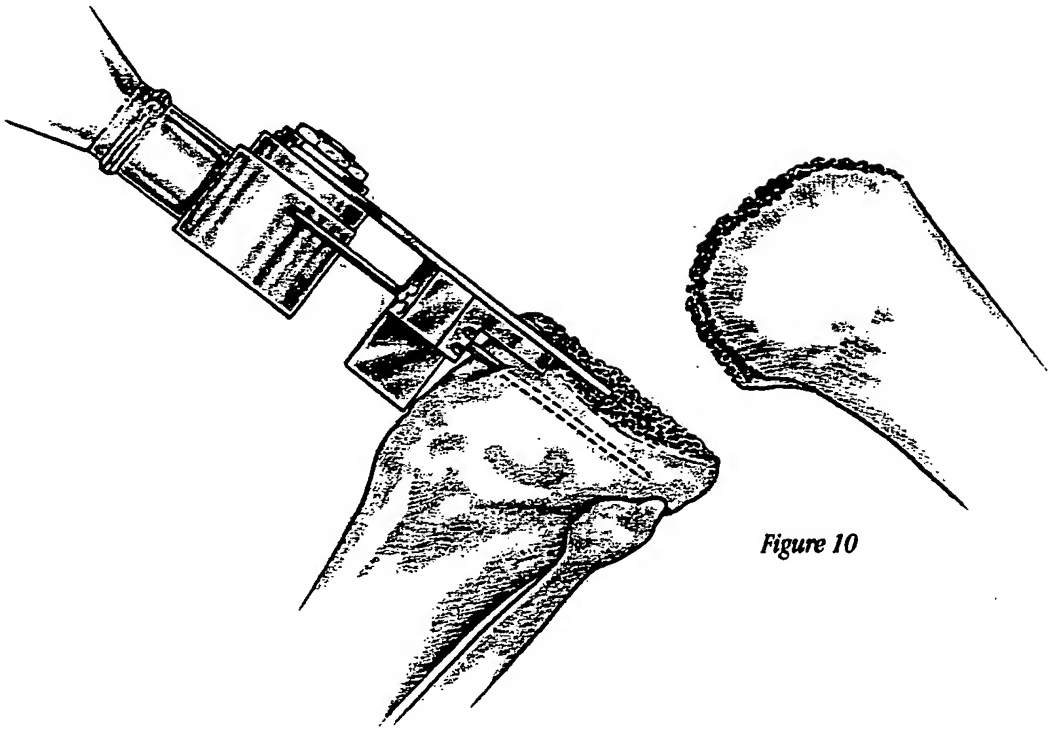


Figure 10

TIBIAL ALIGNMENT CHECK AND SIZING

At this time the tibial viewing plates can be used to size the proximal tibia *(Figure 11)*. Once the correct size has been chosen, place the appropriate tibial drill guide with an 11 mm collet onto the cut surface of the tibia. The handle of the drill guide should be aligned with the medial third of the tibial tubercle. Place the long alignment rod through the handle *(Figure 12)*.

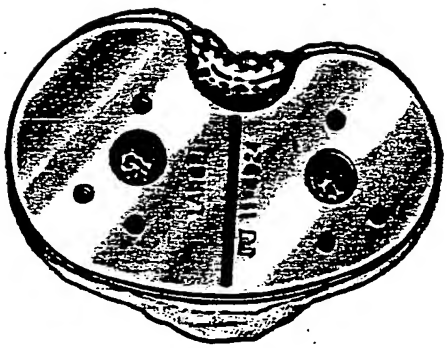
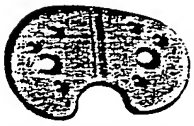


Figure 11



Tibial Viewing Plate
11-4920
11-4922
11-4924
11-4926
11-4927

Tibial Drill Guide
11-4700
through
11-4704

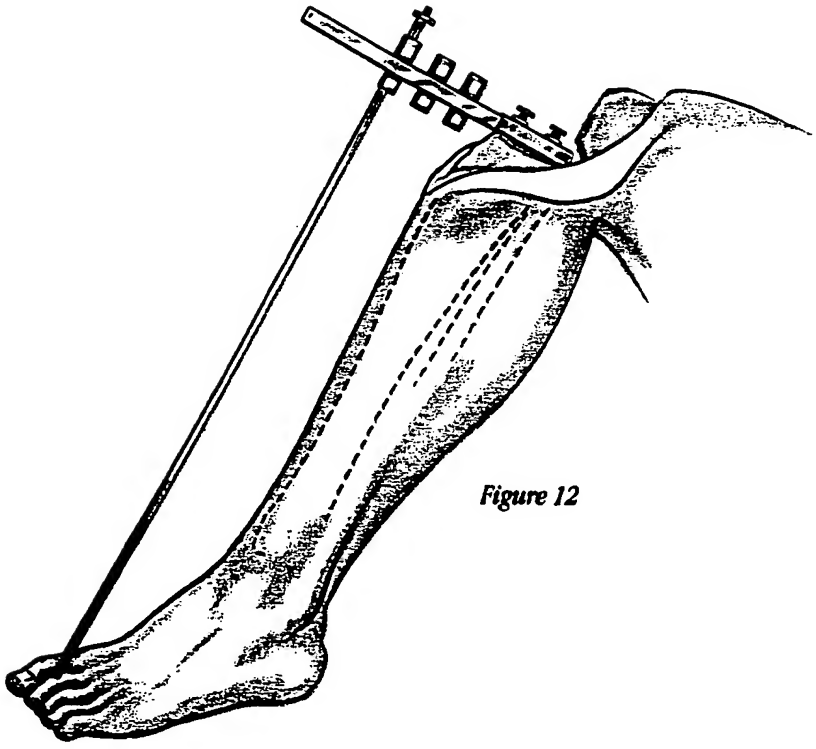


Figure 12

Extramedullary
Alignment Rod
11-4861

11 mm Tibial Drill
Guide Collet
11-4706

11 mm Tibial Drill
71-4602

11 mm Tibial Punch
71-4604

The alignment rod should center on the distal tibia in the coronal and sagittal planes, thus assuring that the tibial cut is perpendicular to the long axis of the tibia. Secure with two ⅛" push pins. Drill the supracondylar bone with the 11 mm drill to the stop *(Figure 13)* and then use the 11 mm punch to impact the remaining bone *(Figure 14)*. It is not necessary to punch if a tibial long stem is to be used. Remove the revision tibial drill guide.

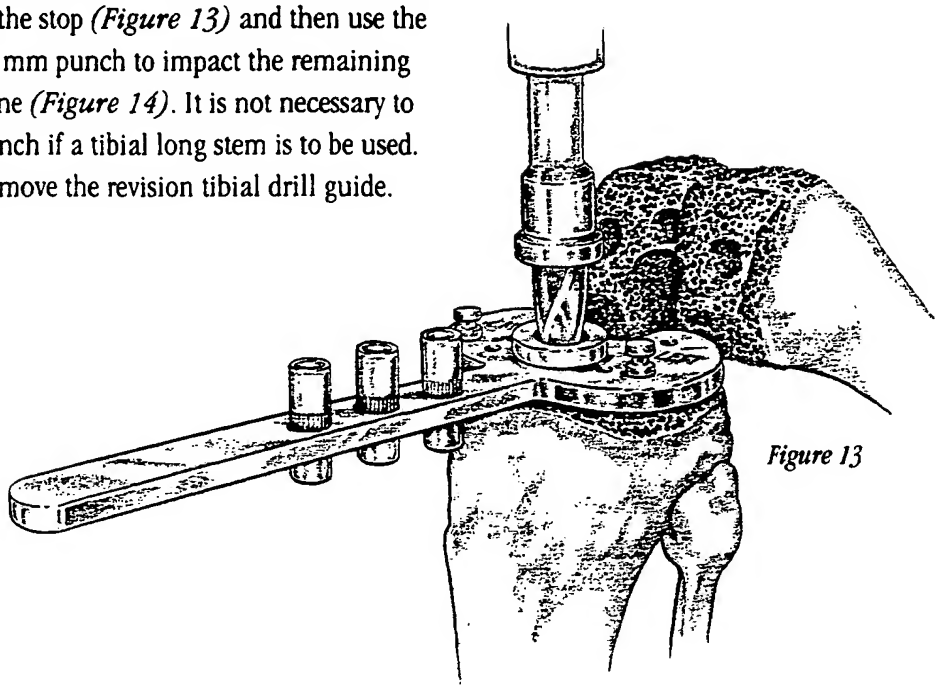


Figure 13

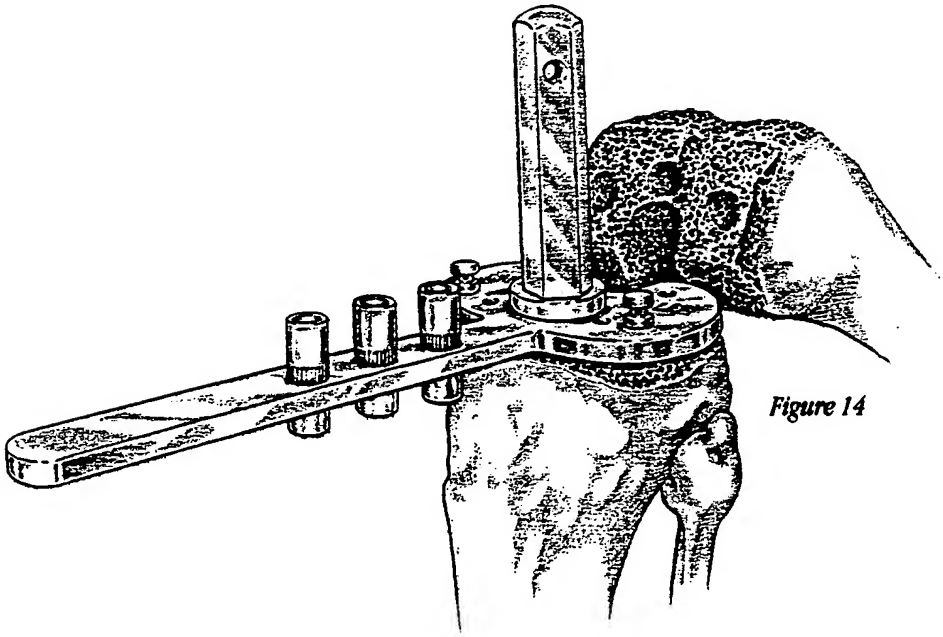


Figure 14

FEMORAL RESECTION

Place retractors under the medial and lateral collateral ligaments adjacent to the femoral epicondyles so that the distal articular surface of the femur is fully exposed.

Open the femoral intramedullary canal with a 9.5 mm drill bit *(Figure 15)*. The distal femoral alignment guide must be set for a 7° valgus angle. The angle cut must also be set for the appropriate left or right knee, so that the coronal cut on the femur is in the correct degree of valgus in relation to the intramedullary stem of the component. Tighten the set screw *(Figure 16)*.

Femoral Drill–9.5 mm
11-4947

Femoral
Intramedullary
Alignment Guide
11-4862

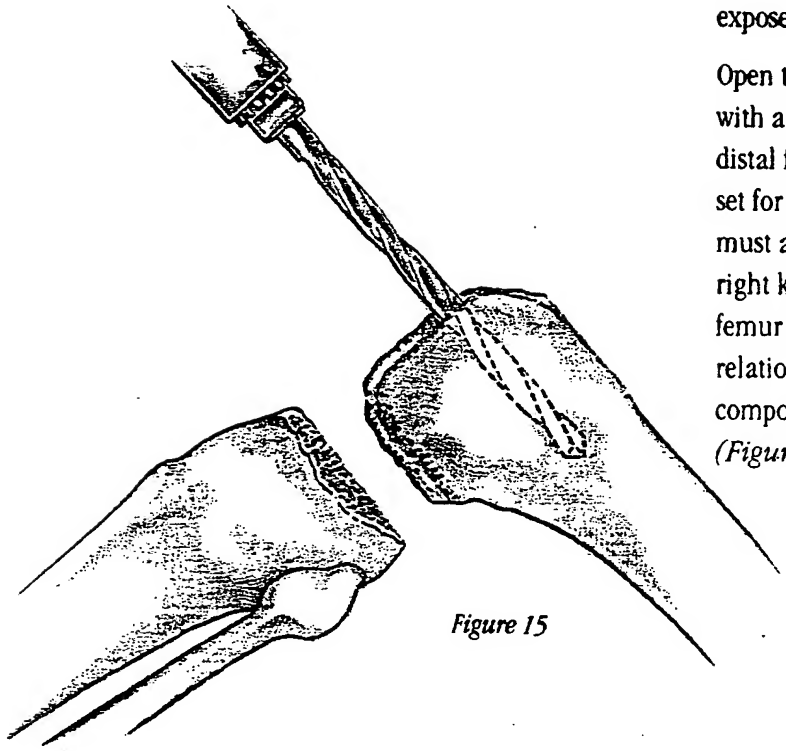


Figure 15

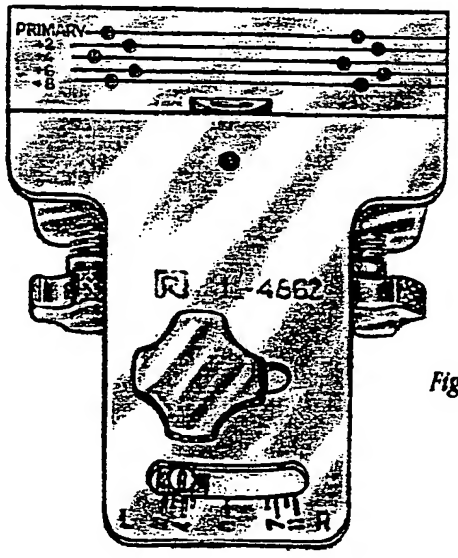


Figure 16

Fluted Intramedullary Rod
11-4859

Retract the cannulated screws on the paddles. Insert the intramedullary rod through the alignment guide and into the canal. Slowly, advance the alignment guide until the paddles of the guide contact the most prominent portion of the distal femur *(Figure 17)*. In cases of asymmetric femoral bone loss, rotate the appropriate cannulated screw on the paddles until the end of the screw contacts the bone surface to further stabilize the assembly. Rotate the alignment assembly into neutral rotation. Since the posterior condyles are most likely deficient, rotation will have to be assessed on the basis of the femoral epicondyles, the lateral one being slightly posterior to the medial epicondyle *(Figure 18)*.

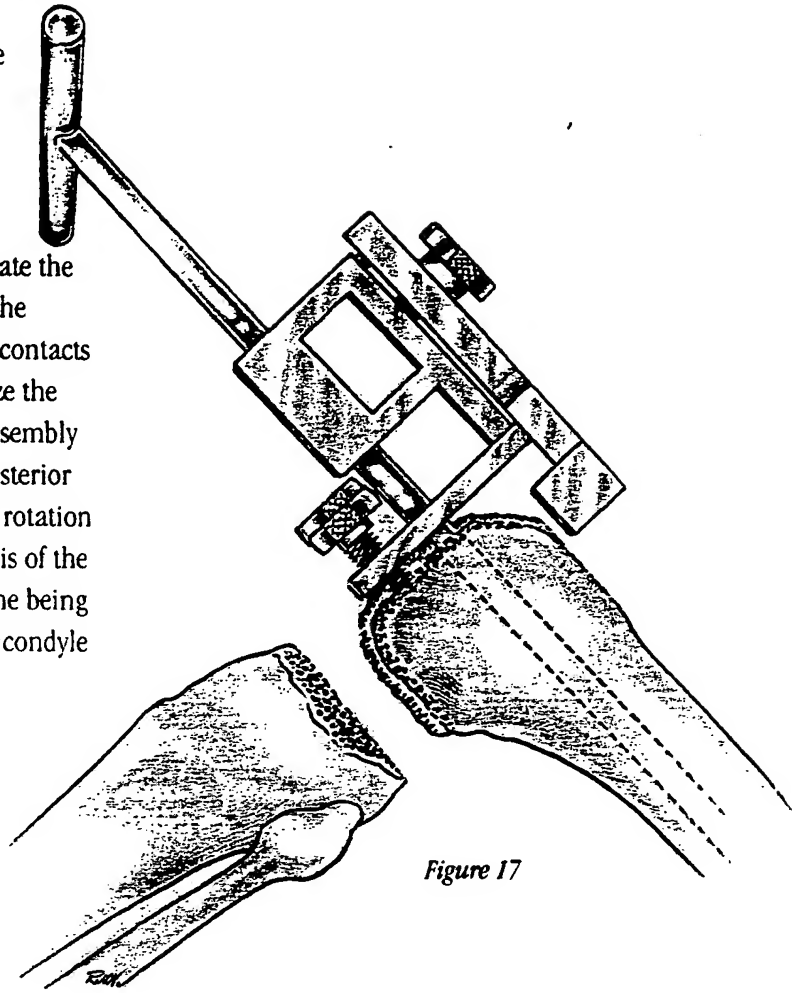


Figure 17

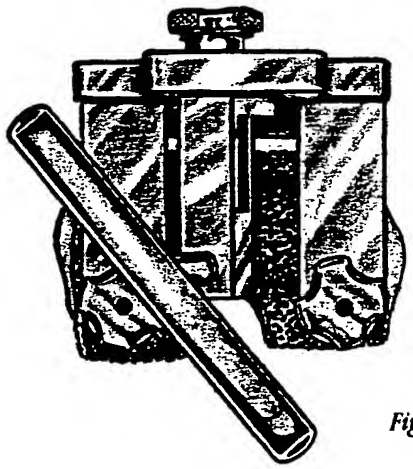


Figure 18

Insert a 1/8" pin or bone spike through the cannulated screw in the lateral paddle. Usually it is necessary to lock only one paddle to secure the rotational orientation of the cutting block. Attach either the slotted or nonslotted distal femoral cutting block to the femoral alignment guide and use the tower and extramedullary alignment rod as a check of the intramedullary position *(Figure 19)*. The alignment rod should point to the radiographic marker on the center of the femoral head. When trying to determine the level of distal femoral cut, the primary objective is to approximate where the original joint line was and to make a cut with the appropriate amount of femoral valgus, at a known distance from the "original" joint line.

Distal Femoral
Cutting Block
11-4863

Slotted Distal Femoral
Cutting Block
11-4669

Extramedullary
Alignment Tower
11-4667

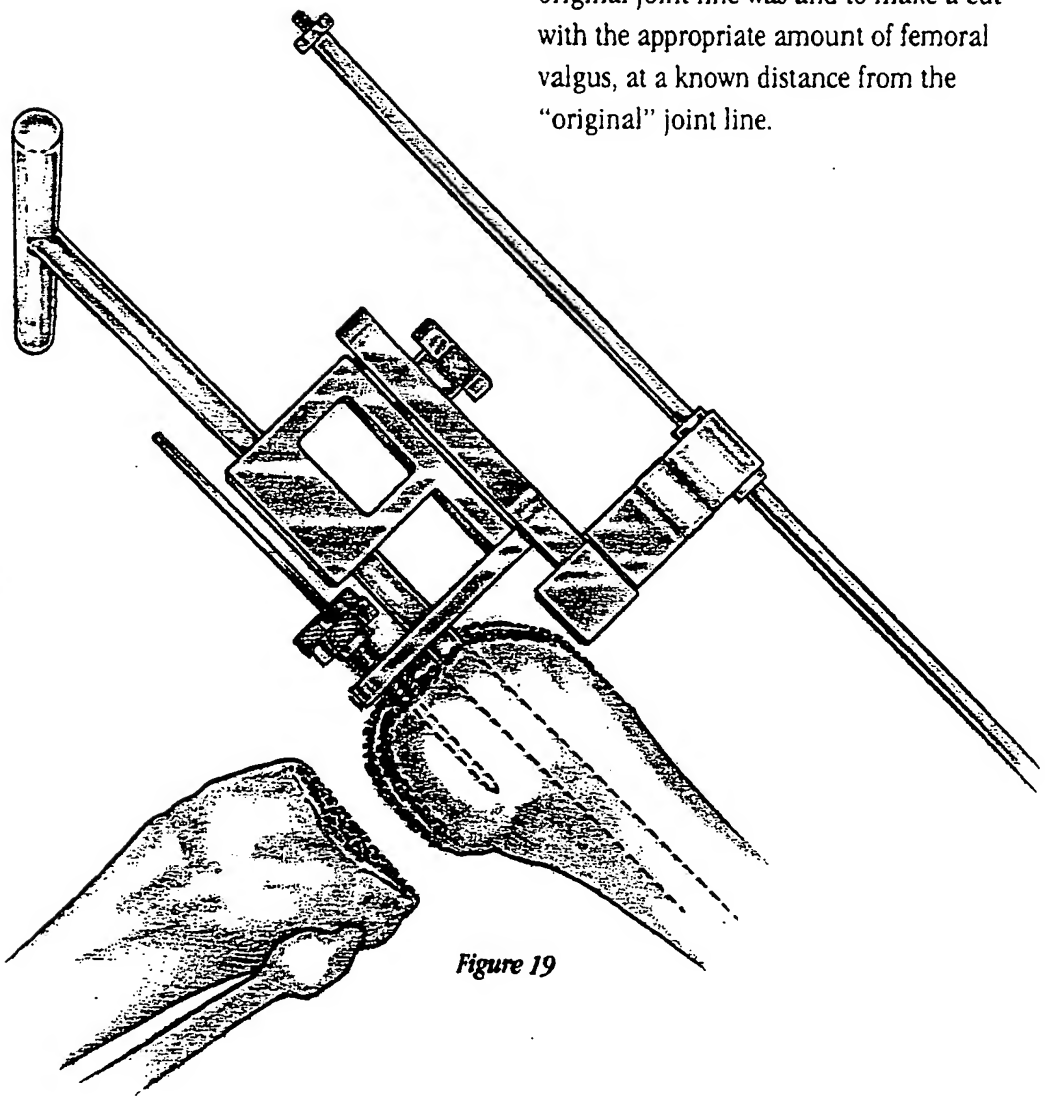


Figure 19

Knowledge of the available prosthesis is helpful in determining the level of femoral cut because the femoral implant must be built up to approximate this "original" joint line. The primary GENESIS femoral components are 7.5 mm thick, and the conversion module is 4 mm thick. If additional bony defects are present on the distal femur, an additional 4 mm of defect may be filled with distal femoral wedges. *(Femoral Wedge Technique follows on page 24.)* Using two 1/8" drill bits, drill through the holes marked "+6" on the distal femoral cutting block *(Figure 20)*. This will allow the block to be moved distally so as to remove as little bone as possible from the distal femur. Remove the intramedullary rod, the laterally placed bone spike or drill bit, and the alignment guide. Move the distal femoral cutting block to the appropriate level of resection by lifting it off of the drill bits and replacing it at the desired level. Remember that you are adding 11.5 mm of component to this level of resection with the addition of the femoral component and conversion module.

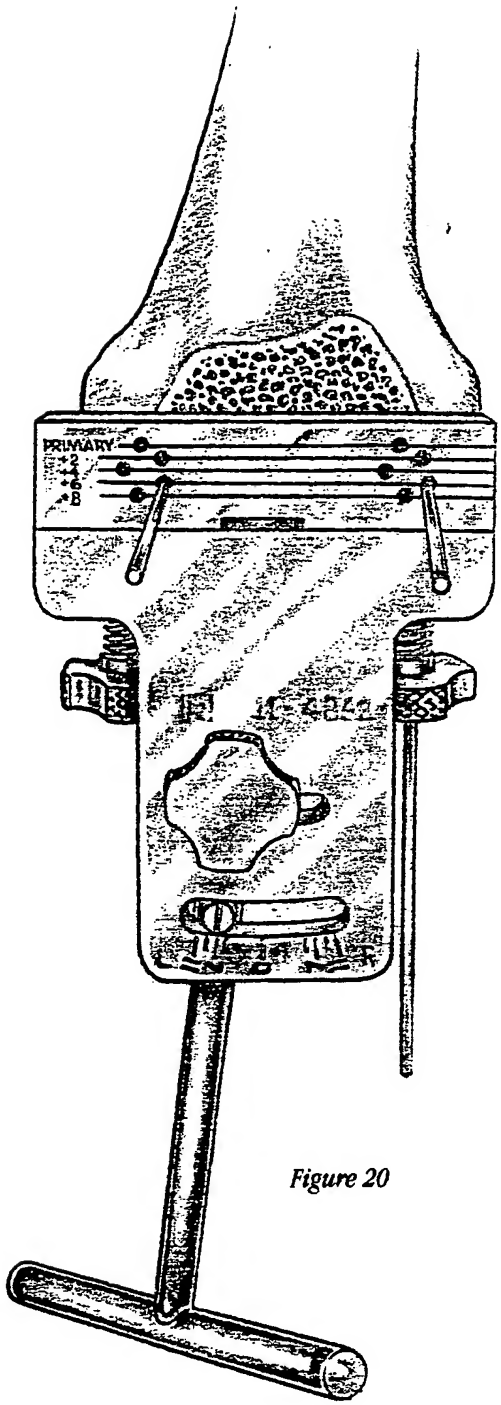
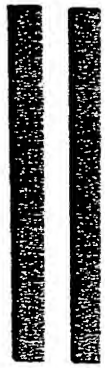


Figure 20

Resect the distal portion of the femur by cutting across the distal aspect of the cutting block with a GENESIS sawblade *(Figure 21)*. If it is preferable to cut through a slot, then use the slotted distal femoral cutting block *(Figure 22)*. Take care to keep the GENESIS sawblade flat against the cutting guide. The use of a rigid sawblade will allow greater accuracy in the cut. Complete the cut with the saw after removal of the cutting block and drill bits.

The cuts should be checked by means of a viewing plate or parallel bars. Any uneven spots should be leveled with a saw or file.



Parallel Bars
11-4886

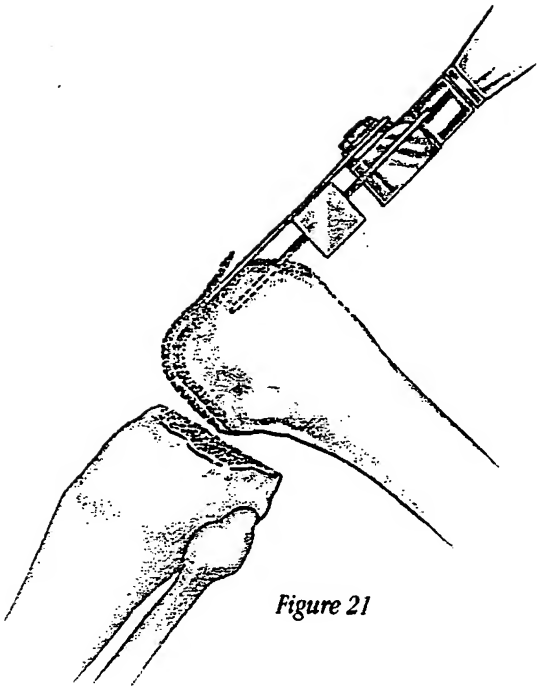


Figure 21

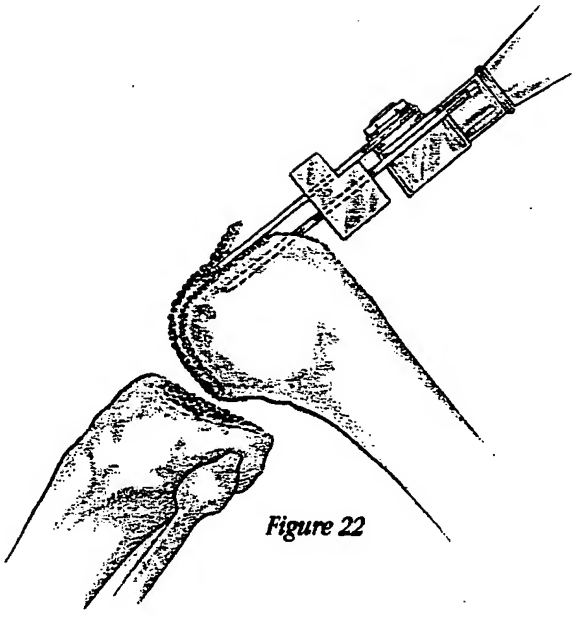


Figure 22

Spacer Block
11-4970
through
11-4975

FEMORAL COMPONENT SIZING

After the proximal tibia and distal femoral cuts have been made, measure the remaining femoral bone in terms of its medial-lateral and anterior-posterior width *(Figures 23 and 24)*.

Next, measure the flexion and extension gaps *(Figures 25 and 26)*. There are 8, 10, 12, 15, 20, and 25 mm spacer blocks available for these measurements. The 8 mm spacer block is actually 15.5 mm in thickness because it corresponds to the actual thickness of the combined femoral component, tibial base plate, and 8 mm articular insert. Likewise, the 10 mm spacer block is 17.5 mm thick. Notice that in Figure 24, a 4 mm adaptor plate has been added to the spacer block in extension. This adaptor plate is added because by adding a conversion module to the femoral component, an additional 4 mm is added distally to the component.

When sizing the femoral component, the objective is to place implants on the knee with the appropriate augmentation such that with a standard tibial polyethylene component in place, the flexion and extension gaps will be even and the joint line restored.

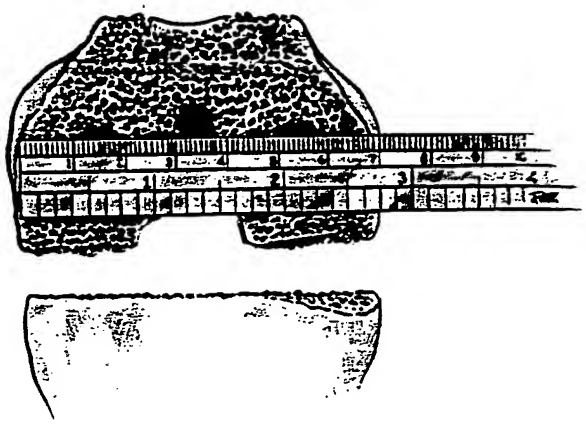


Figure 23

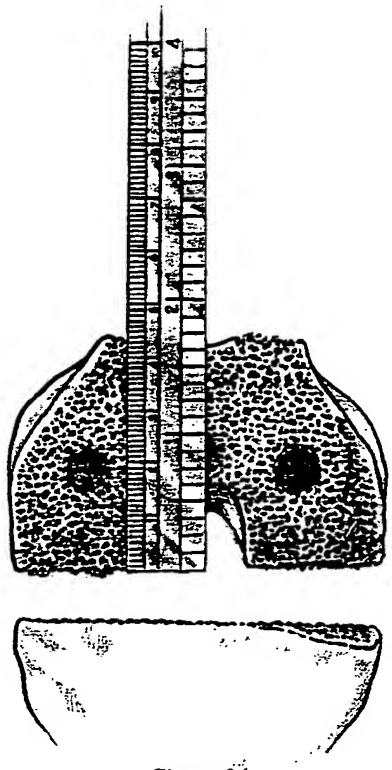


Figure 24

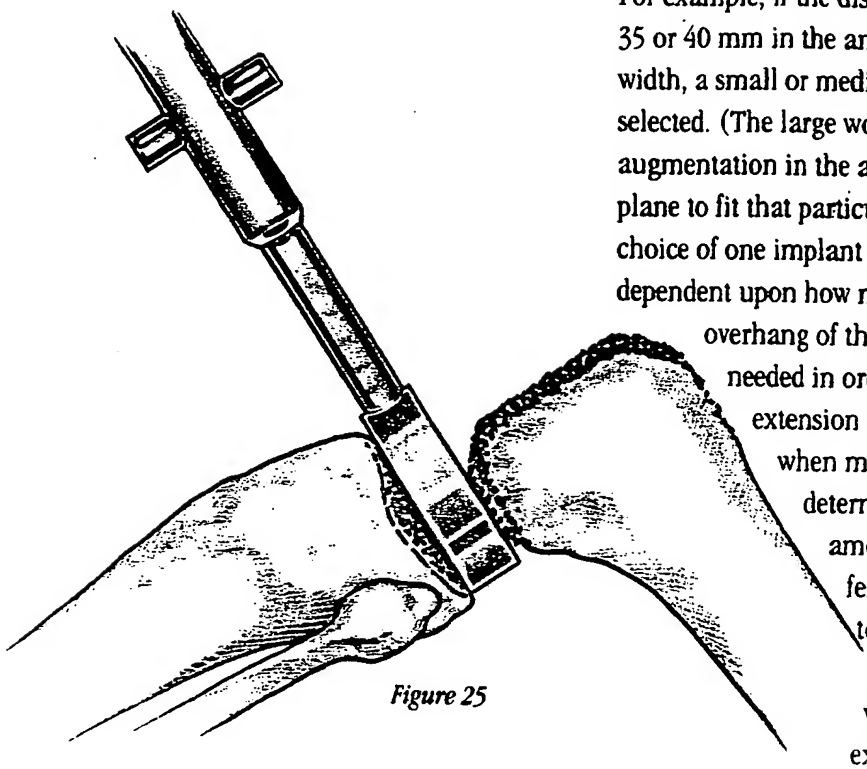


Figure 25

For example, if the distal femur measures 35 or 40 mm in the anterior-posterior width, a small or medium component is selected. (The large would require augmentation in the anterior-posterior plane to fit that particular femur.) The choice of one implant versus the other is dependent upon how much posterior overhang of the femoral implant is needed in order to fill the extension space. However, when making this determination, the amount of distal femoral augmentation to be added must be considered, as this will change the extension gap.

(OTHER SIZING OPTIONS: Measure size of removed components or contralateral joint.)

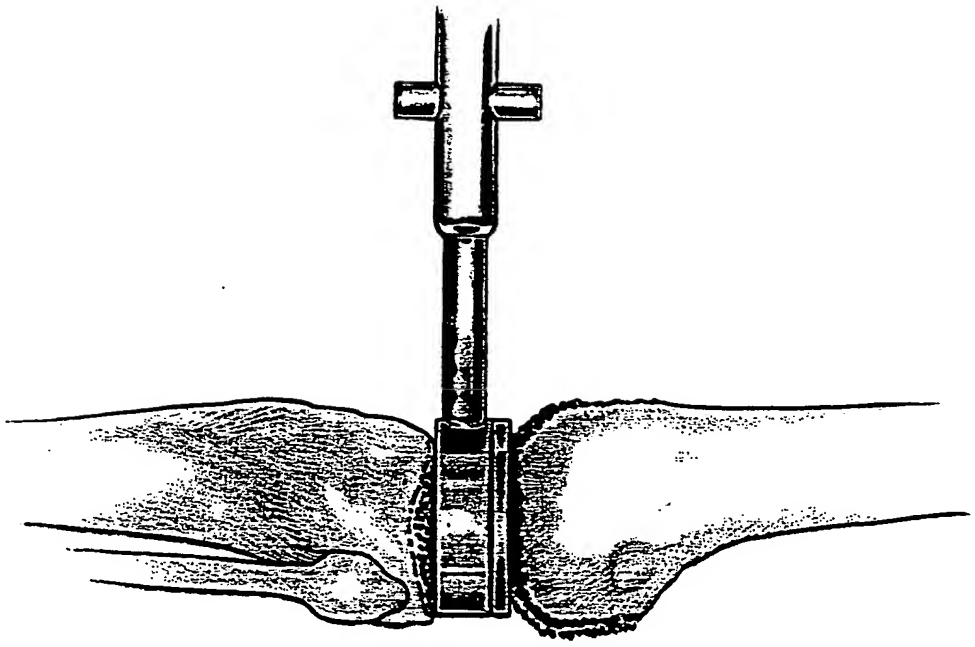


Figure 26

DISTAL FEMORAL WEDGE TECHNIQUE

Frequently, bony defects exist on the distal femur. In order to restore the original joint line, distal wedges can be placed to augment or build up the deficient condyle. If, after resecting a minimal amount of distal femur, a defect persists on the medial or lateral condyle, you may fill this defect with a 4 mm thick distal femoral wedge. To level the defect so that the wedge will fit properly, simply move your distal femoral cutting block 4 mm proximally from the freshly cut "good" side *(Figures 27 and 28)*. Recut the defective condyle at this level, making sure that the sawblade remains flush against the cutting surface. This technique will leave one condyle recessed 4 mm behind the other. This 4 mm deficit will eventually be filled with a distal femoral wedge which is attached to the femoral implant.

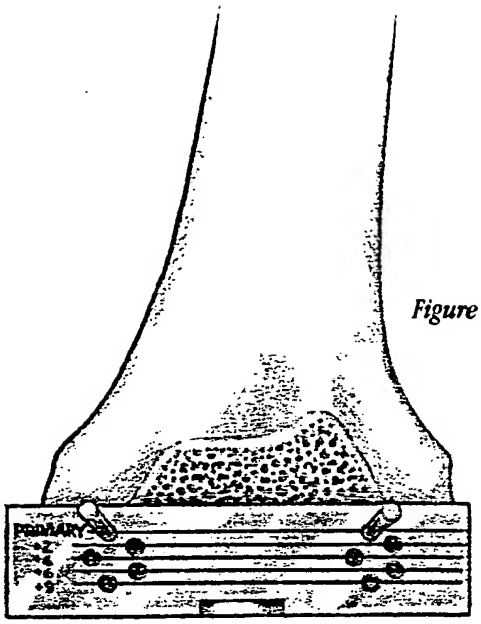


Figure 27

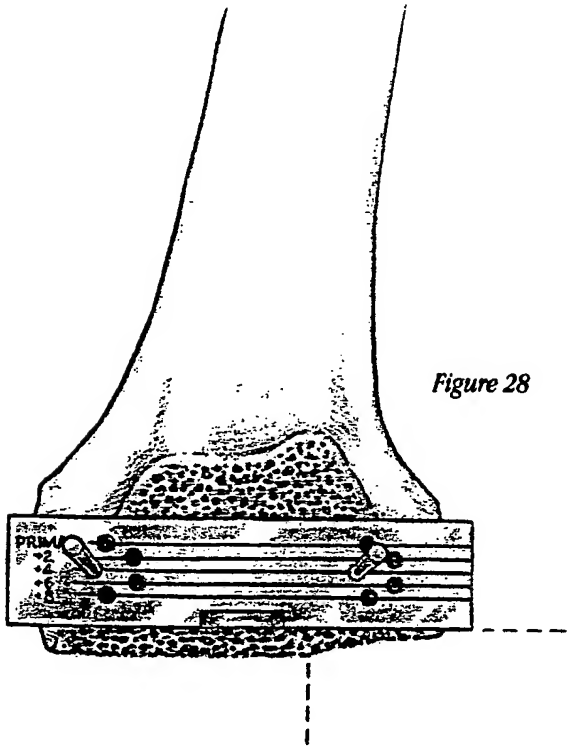


Figure 28

FEMORAL COMPONENT ALIGNMENT

Revision Femoral Drill Guide
11-4834
through
11-4839

Femoral Lug Drill
11-4869

Rotational, medial-lateral, and anterior-posterior orientation of the femoral prosthesis is determined by the revision femoral drill guide. Begin by leveling any high or uneven spots on the anterior femur. Choose the correct size drill guide based upon previous flexion and extension gap measurements. Place this jig flat against the distal femur. The drill guide incorporates an anterior reference plate which is placed flat against the anterior femur. The guide can be stabilized by placing pins or bone spikes through the holes of the anterior plate and into the anterior cortex. Further, use the relationship of the handles on this guide in reference to the femoral epicondyles to place the prosthesis in neutral rotation relative to the coronal plane of the distal femur. A second check to ensure neutral rotation is to align the posterior surface of the revision femoral drill guide with the flat cut tibial surface so that the two planes are parallel. Be sure that the jig is flat and contacting the distal cut surface. Lastly, the jig should be centered in the medial-lateral plane. When correct positioning of the guide has been assured, place at least two ⅛" drills in the anterior ledge and drill two $\frac{9}{32}$" holes for the femoral prosthesis fixation pegs using the twist drill *(Figure 29)*. Drill to the depth provided by the stop on the drill.

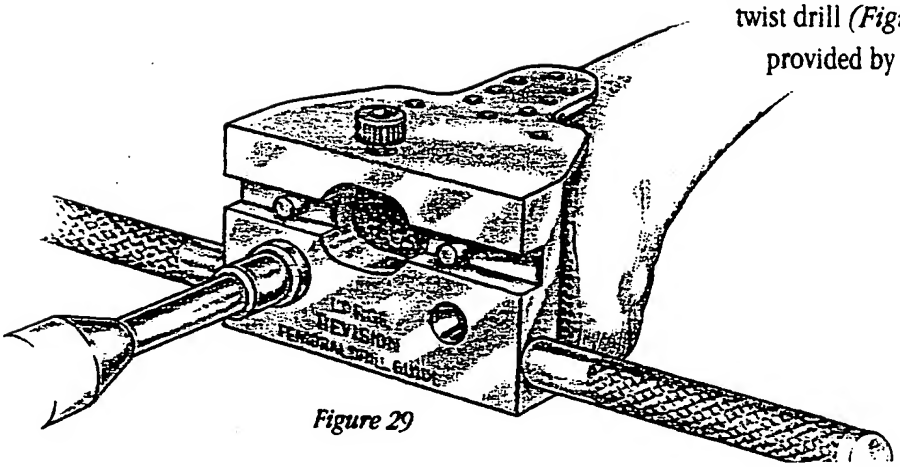


Figure 29

FEMORAL LONG STEM REAMING

Modular Revision Femoral Collet
11-4840
through
11-4843

Modular Long Stem Reamer Sleeve
11-4845
through
11-4848

At this point, the femoral intramedullary canal is reamed to accept a femoral long stem component. The approximate diameter and length of the stem is determined from preoperative X-rays. Place the 10 mm revision femoral drill guide collet into the revision femoral drill guide *(Figure 30)*. Tighten the set screw. Place the appropriate sized reamer sleeve onto each of the reamers. The reamer, reamer sleeves, and revision femoral drill guide collets are color-coded so that the correct instruments can be easily matched during surgery.

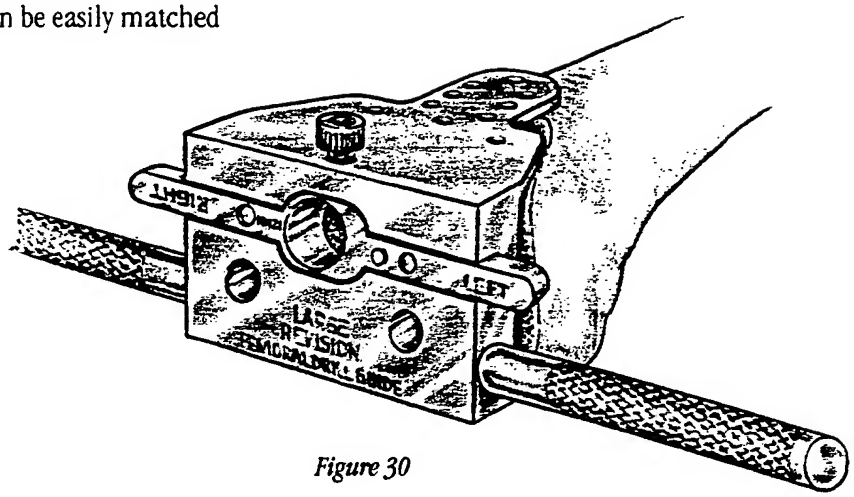


Figure 30

Begin with the 10 mm reamer and ream through the drill guide to the appropriate depth *(Figure 31)*. Each reamer is calibrated and this measurement is read from the distal face of the revision drill guide. Continue this process with successively larger diameter reamers and collets until you hear the chatter of the reamer hitting cortical bone. To press-fit the long stem, choose the same diameter trial and implant pegs as last reamed. If you prefer a cement mantle, choose a stem with a diameter 2 mm less than was last reamed. Remove the revision femoral drill guide and drill sleeve from the distal femur, leaving the reamer in place.

Revision Reamer
11-4982
11-4984
11-4978
11-4979

NOTE: Because of the interior dimensions, each size of femoral component has a maximum allowable diameter of femoral stem that can be used. The limitations are:

Femoral Component Size	Maximum Stem Diameter
Small	16 mm
Medium	18 mm
Large	20 mm
Extra-Large	20 mm
Magnum	22 mm
Magnum Plus	24 mm

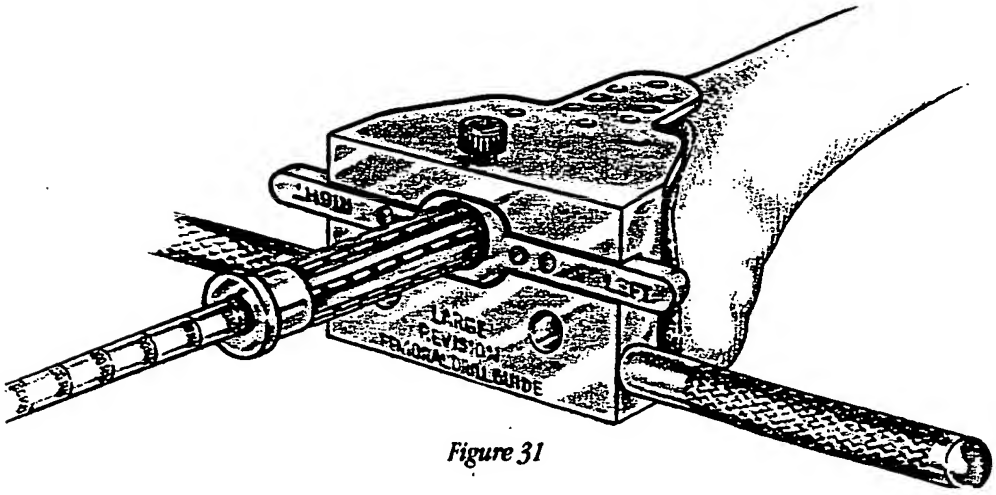
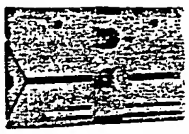
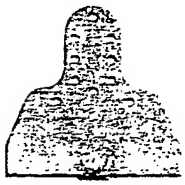


Figure 31



Revision A/P Cutting Block
11-4820
11-4822
11-4824
11-4826
11-4828
11-4830



Revision Anterior Ledge
11-4831

ANTERIOR AND POSTERIOR FEMORAL RESECTION

After reaming to the correct depth, attach the correctly sized revision A-P cutting block to the distal femur by sliding it down over the reamer and inserting the two posts of the A-P cutting block in the distal femoral fixation holes *(Figure 32)*. Adjust rotation using the handles on this guide in relation to the femoral epicondyles. If little distal condyle is present, the anterior ledge can be added and spiked down at the appropriate level on the anterior femur to assist in the stabilization of the A-P cutting block. This anterior ledge should not contact the femur because it is designed so that an anterior cut can be made through the slot between the anterior ledge and A-P cutting block *(Figure 33)*.

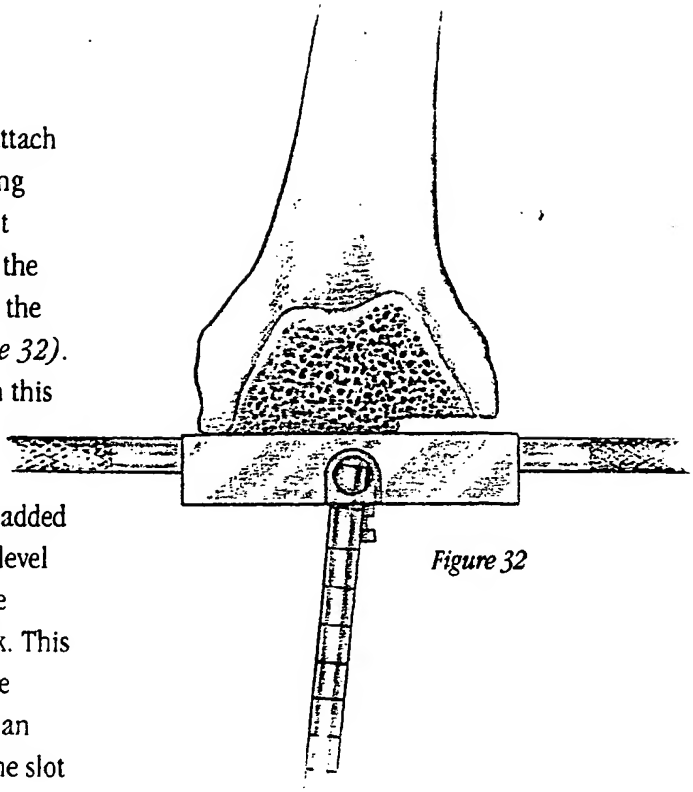


Figure 32

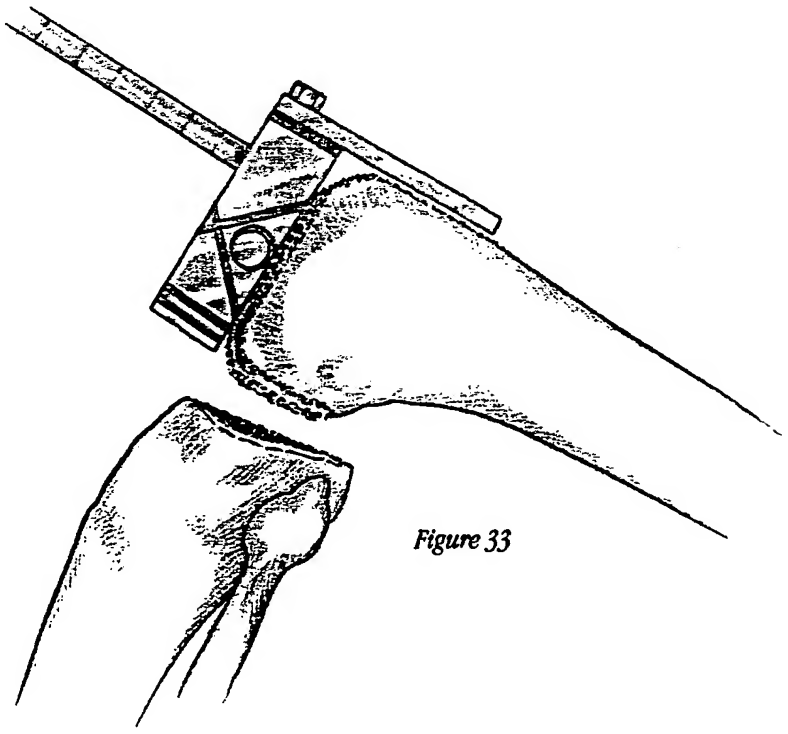


Figure 33

The point of intersection of the anterior cut with the femur should be carefully assessed prior to cutting to ensure that femoral notching does not occur. Before cutting, use the anterior reference guide placed on the superior surface of the block to assess the level of the cut. This should confirm that the anterior femoral cortex is not notched. Once the revision A-P cutting block is placed in the correct position, recut the anterior and posterior cuts if necessary *(Figure 34)*. The sawblade should remain flush against the cutting guide during this procedure. If it is preferable to cut through slots, attach the femoral adapter block to the A-P cutting block prior to making cuts. If the anterior ledge has been used, an anterior cut can be made between the block and the plate if necessary.

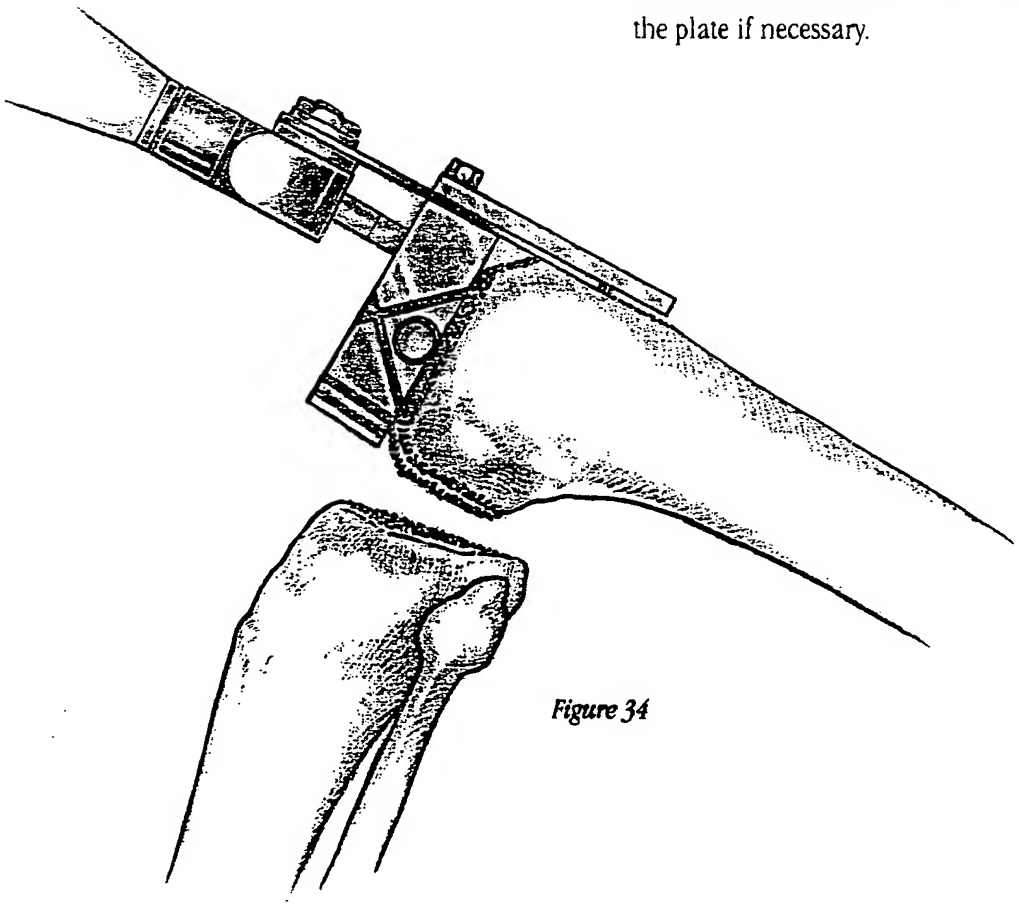


Figure 34

POSTERIOR WEDGE TECHNIQUE

If the posterior level of resection falls below the posterior femoral bone, this space can be filled with posterior femoral wedges attached to the femoral component. To correctly shape the bone to accept a posterior wedge, begin by making a cut through the slot which is 4 mm above the posterior cutting surface on the A-P cutting block *(Figure 35)*. If the posterior condyle or condyles are leveled by the cut, a 4 mm posterior wedge should be added to the correct side of the femoral component to accommodate for this defect. If this level of resection still falls below the posterior condyles, it may be necessary to fill this defect with an 8 mm posterior wedge.

Raise the level of resection to the slot which is 8 mm above the posterior cutting surface of the A-P cutting block. Recut the posterior condyle(s). (NOTE: It is important to remember that both the distal and posterior sides of the femoral component cannot be augmented 8 mm at the same time using standard components. If an 8 mm posterior wedge is used, a conversion module or a distal only wedge can be used. If a conversion module and distal wedge are used, the posterior side can only be augmented 4 mm.)

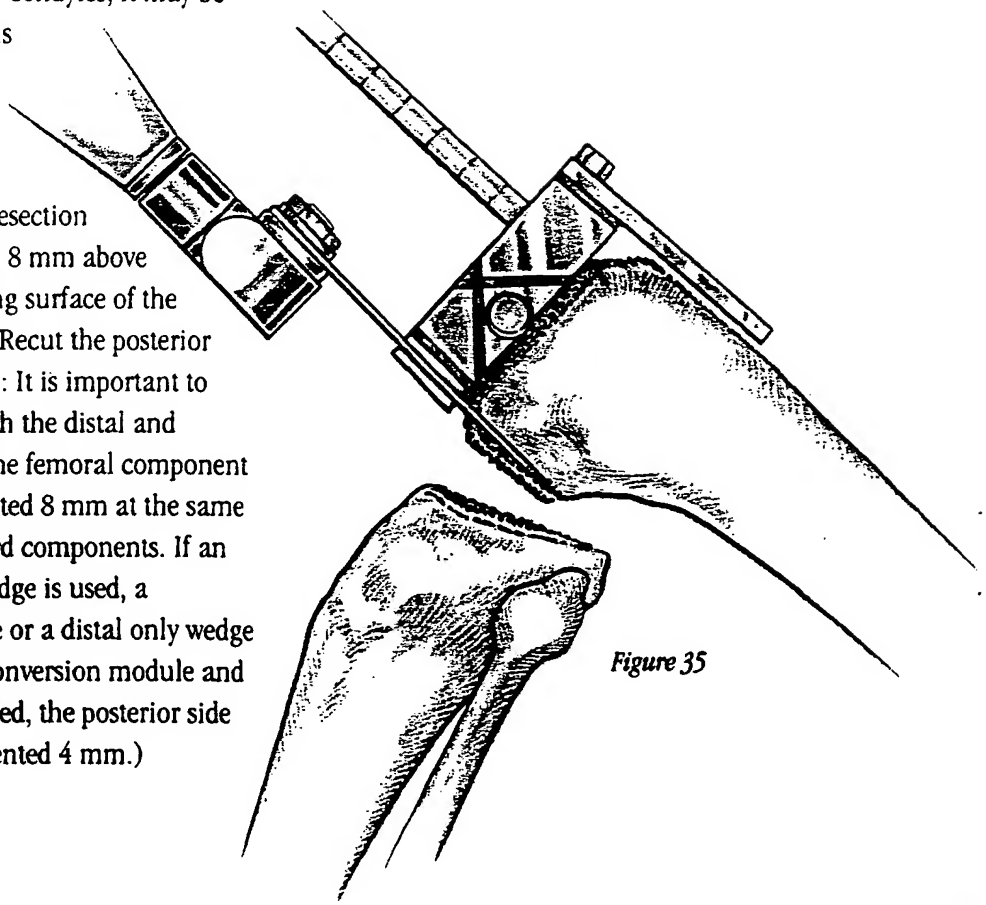


Figure 35

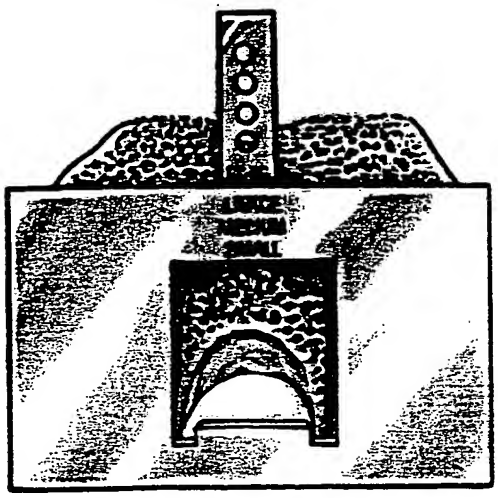


Figure 36

Additional Femoral Cuts Performed When Using a Posterior-Stabilized or Posterior-Stabilized With Long Stem Femoral Component

After performing the anterior and posterior femoral cuts, prepare the femur for the posterior-stabilized housing. Remove the femoral intramedullary reamer and revision A-P cutting block. Attach the femoral notch guide to the distal femur by inserting the two posts on the guide into the distal femoral fixation holes *(Figure 36)*. Ensure that the femoral notch guide is centered on the distal femoral surface in the medial-lateral plane and that it is flat against the distal femur. The anterior stylus can be used to stabilize the jig against the femur *(Figure 37)*.

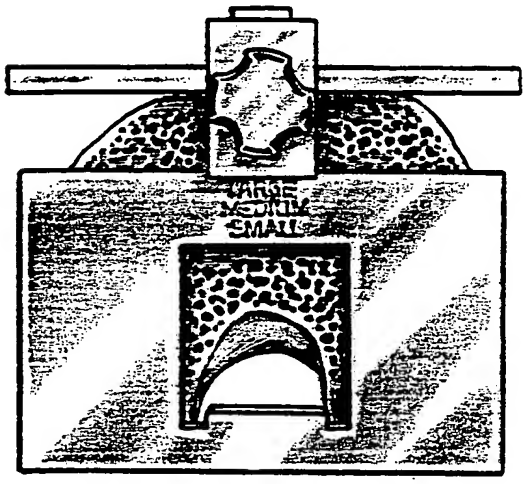
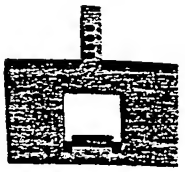
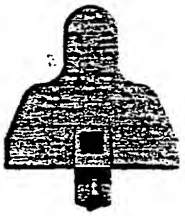


Figure 37



Posterior-Stabilized
Femoral Notch Guide
11-4811
Small–X-Large
11-4813
Magnum–Magnum
Plus



Posterior-Stabilized
Femoral Notch Guide
Stylus
11-4812
Small–X-Large
11-4814
Magnum–Magnum
Plus

Posterior-Stabilized
Reamer Dome
11-4818

Patellar Reamer Shaft
11-4937

Posterior-Stabilized
Housing Osteotome
11-4816

Attach the posterior-stabilized reamer dome to the patellar reamer shaft. Prepare the distal femur by reaming through the femoral notch guide until the stop on the reamer dome contacts the femoral notch guide *(Figure 38)*. Remove the reamer.

A small amount of excess bone may remain anteriorly, medially, or laterally. An osteotome has been provided which precisely matches the interior dimensions of the femoral notch guide. Insert the osteotome to cut away any bone that may remain *(Figure 39)*. A stop has been manufactured on the osteotome to prevent the osteotome from cutting too deep. When completed, the amount of bone removed will correspond to the dimensions of the conversion module's cam and tibial eminence.

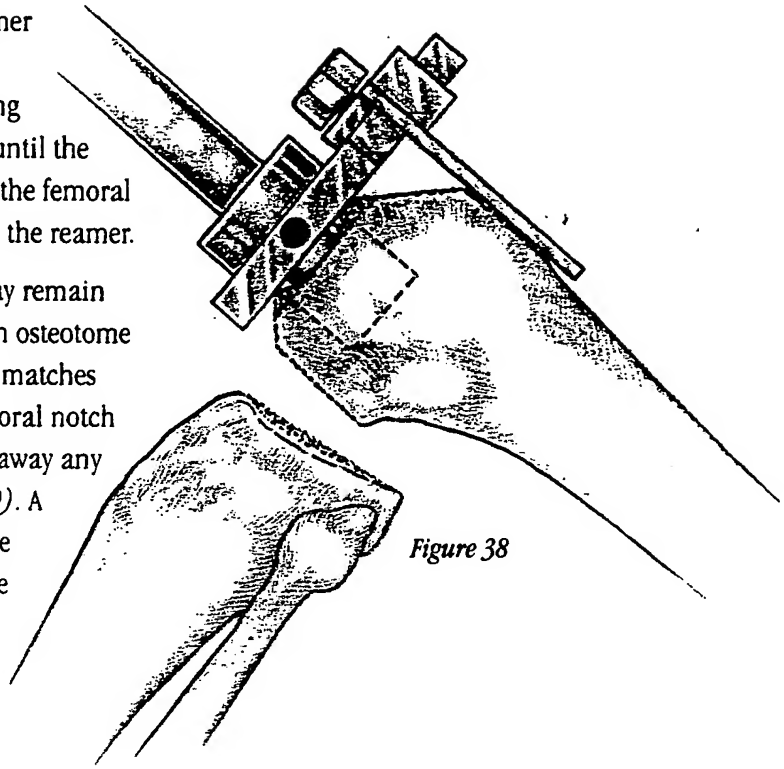


Figure 38

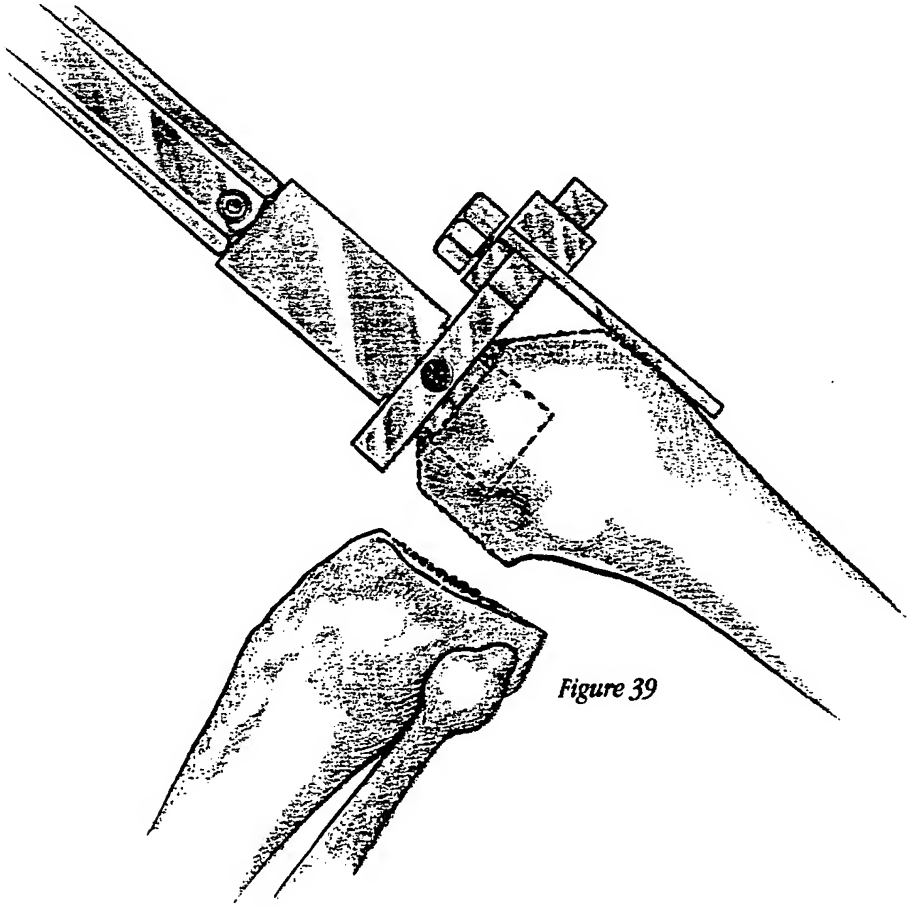


Figure 39

Verification of the correct depth is determined by inserting the housing sizer through the femoral notch guide *(Figure 40)*. The housing sizer will only mate with the femoral notch guide in one way because a channel has been machined on the housing sizer to correspond to the appropriate area on the distal aspect of the femoral notch guide. Insert the housing sizer through the femoral notch guide until it "bottoms out," verifying that the correct depth has been reamed for both the conversion module and tibial eminence. If the housing sizer does not bottom out, additional resection is required in the appropriate area.

NOTE: The housing sizer should never be impacted into the bone.

Posterior-Stabilized Housing Sizer 11-4815

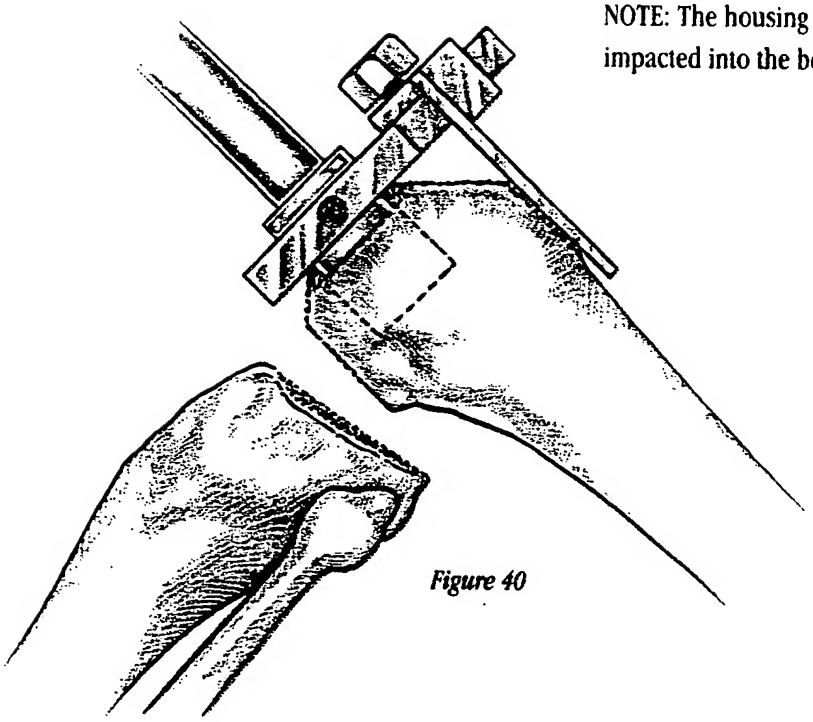
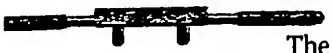


Figure 40

ANTERIOR AND POSTERIOR CHAMFER RESECTION



Posterior-Stabilized Chamfer Cutting Block
11-4802
11-4804
11-4806
11-4808
11-4810

The anterior and posterior chamfer cuts are now performed. If it is preferable to perform the chamfer cuts through slots, this can be done using the revision A-P cutting blocks. If it is preferable to perform the chamfer cuts over the top of a cutting block, this can be done using the posterior-stabilized chamfer cutting blocks. After the removal of the femoral canal reamer and A-P cutting block, place the posterior-stabilized chamfer cutting block on the distal femur by inserting the two posts of the chamfer block in the distal femoral fixation holes. Recut the anterior and posterior chamfers, if necessary *(Figure 41)*. Take care that all of the cuts are accurate. Since the blade meets the bone at an oblique angle, there is a tendency for the blade to skive away from sclerotic or hard bone, resulting in removal of too little bone. All cuts should be carefully assessed with a viewing plate or parallel bars.

After the principle femoral cuts have been made, the joint should be fully debrided.

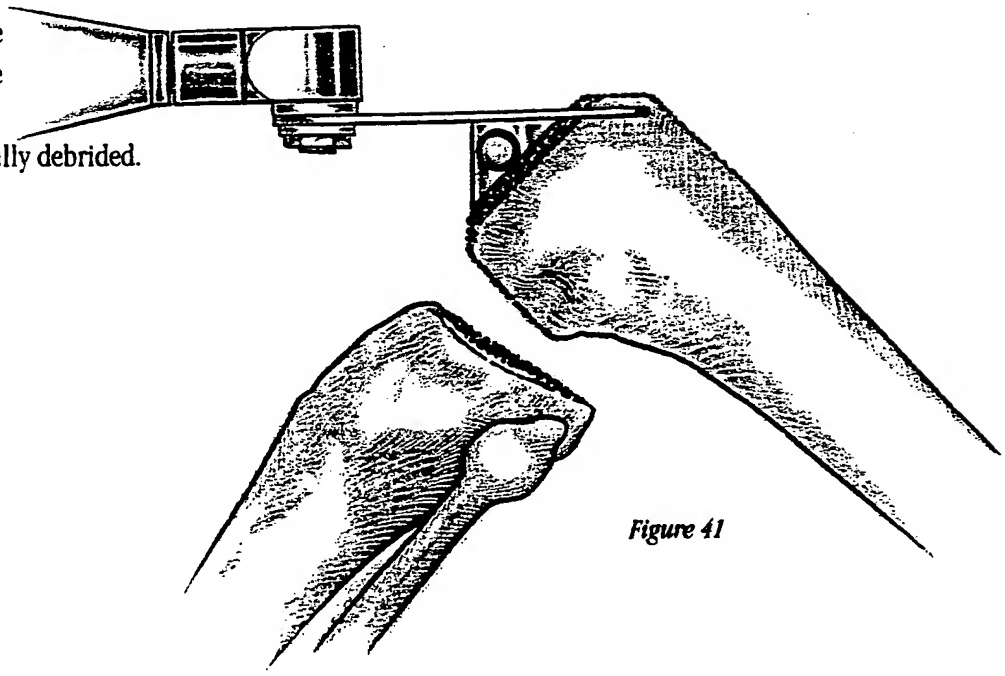


Figure 41

TIBIAL LONG STEM REAMING

Modular Tibial Drill Guide Collet
11-4705 – 10 mm
11-4707 – 12 mm

If a tibial long stemmed component is indicated, ream for the long stem at this time. Place the correctly sized tibial drill guide onto the proximal tibia and pin it in place using two ⅛" drill bits. Place the 10 mm collet into the drill guide. Ream through the collet with a 10 mm reamer and reamer sleeve down to the correct depth, making sure that the reamer follows a path which is perpendicular to the tibial drill guide surface *(Figure 42)*. Read the depth of reaming from the calibrated reamer shaft off of the superior face of the tibial drill guide. If a 12 mm diameter stem is to be used, replace the 10 mm collet with a 12 mm collet and ream in the same manner with the 12 mm diameter reamer and reamer sleeve. If a larger diameter stem is needed, remove the tibial drill guide and ream with successively larger diameter reamers following the previous path.

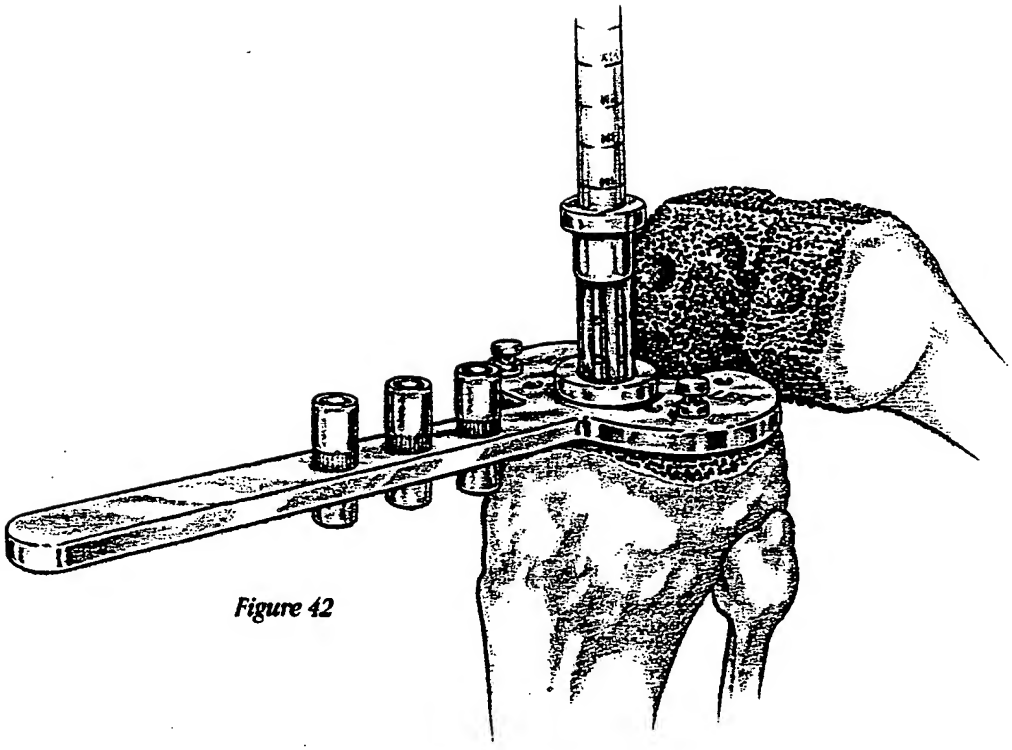


Figure 42

Hemi Wedge Resection Block 11-4617 through 11-4626

Hemi Wedge Resection Rod 11-4615

Hemi Wedge Resection Screw 11-4616

TIBIAL WEDGE TECHNIQUE

If a defect remains on the tibial plateau, prepare the tibia to accept a metal wedge at this time. Two suggested approaches are for the Hemi Wedge and for the Medial-Lateral Tibial Wedge.

Hemi Wedge

Place the tibial trial on the proximal tibia. Assemble the resection guide rod to the tray by screwing in the thumb screw to the threaded hole and sliding the U-shaped portion of the rod around the screw *(Figure 43)*. Tighten the screw. Select either the 10 mm or 15 mm angled wedge block. Attach the block to the rod and slide the block to the anterior tibia. Assess the resection level to ensure the proper size has been selected. To secure the block, insert ⅛" pins or bone spikes through the holes in the block *(Figure 44)*. Remove the rod and tibial trial *(Figure 45)*. Resect the proximal tibia over the angled block.

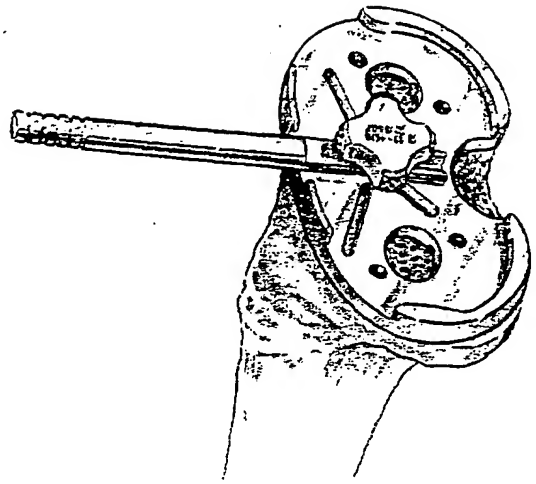


Figure 43

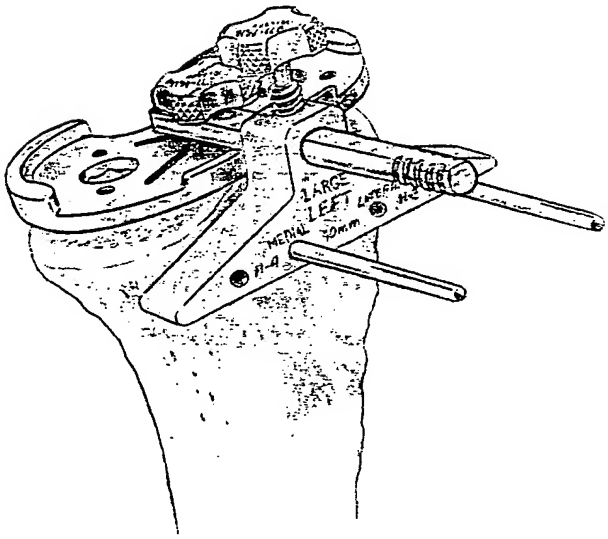


Figure 44

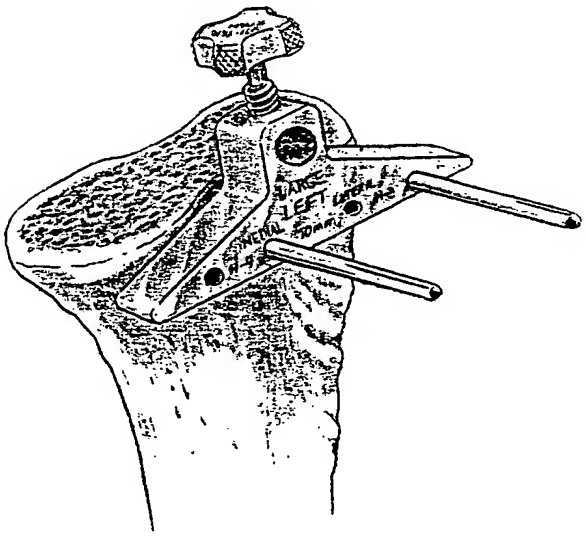


Figure 45

Medial-Lateral Tibial Wedge

Select a tibial trial wedge that approximates the size of the bone deficiency. The wedge trial is temporarily secured to the underside of the tibial tray using a small amount of bone wax *(Figure 46)*. Cover the wedge with methylene blue and place the tibial base trial into correct position. Usually, the bone deficiency will need to be contoured to accept the metal wedge. The methylene blue will transfer from the metal wedge to the tibial bone, indicating where contact has been made. The bone can then be removed with a small burr, to allow complete seating of the wedge and the tibial tray flat on the cut tibial surface *(Figure 47)*. This results in the bone being left anterior and posterior to the metal wedge for most peripheral deficiencies, providing additional support for the wedge. Multiple trial seatings are usually necessary with a small amount of bone removed between each in order to achieve the appropriate fit between implant and bone. The entire bony surface in the area of the deficiency will appear blue, indicating full contact with the bone when the shaping is complete. Once the bone defect has been contoured to accept the wedge, make multiple drill holes in the sclerotic bone to allow cement penetration. Be sure to leave the trial wedge on the tibial base trial for reference when preparing the implants.

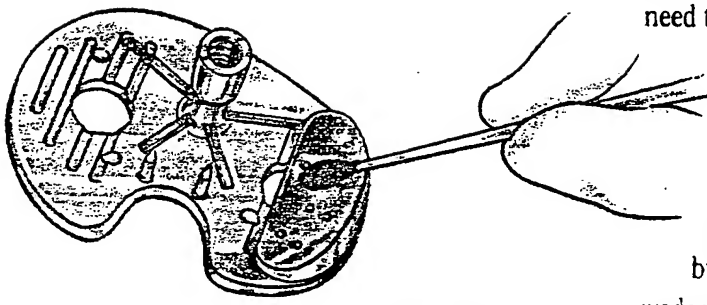


Figure 46

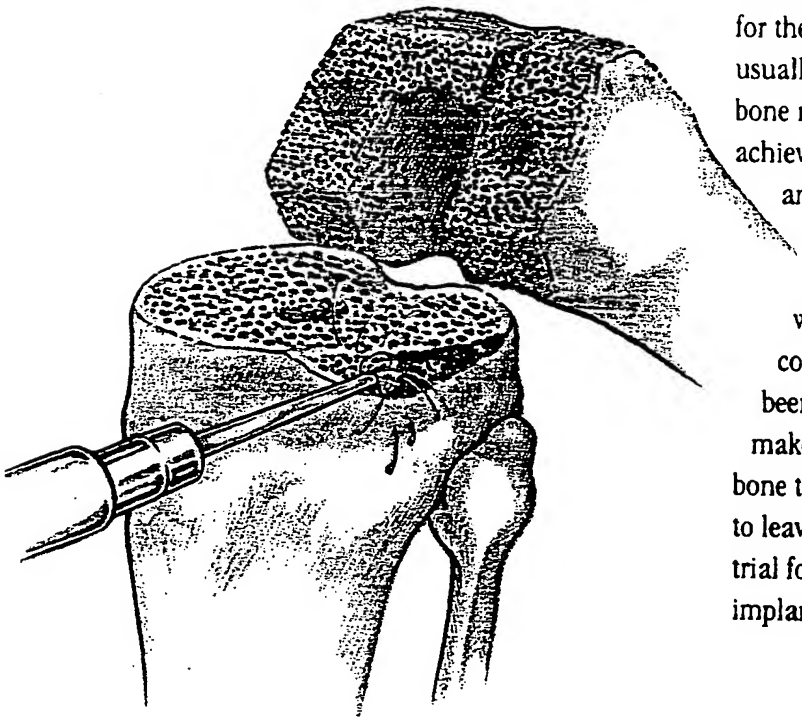


Figure 47

TRIAL COMPONENT SEATING

Flex the knee. Place a wide Hohman or similar retractor posteriorly and subluxate the tibia anteriorly. Select the appropriate trial tibial base. If tibial wedges are to be used, they should be affixed with bone wax. If a tibial long stem is to be used, screw it into the tibial trial at this time. Seat this assembly on the proximal tibia *(Figure 48)*. Choose a tibial size which most completely covers the proximal tibia without overhang of the component. Overhang of the component on the medial aspect of the tibia or impingement against the medial collateral ligament will cause pain. Remove the Hohman retractor and reduce the tibia. Select the appropriately sized femoral trial component, conversion module trial, wedge trials, and long stem trials. Remove the lugs on the femoral trial component. Assemble the conversion module trial on the femoral trial component. If any distal femoral wedges are to be used, place them in the appropriate location at this time. If distal femoral wedges are to be used, Christmas tree trial lugs must be used to tighten this assembly in place *(Figure 49)*. The trial lugs are tightened by hand; however, if only a conversion module is used, tighten the regular trial lugs in place.

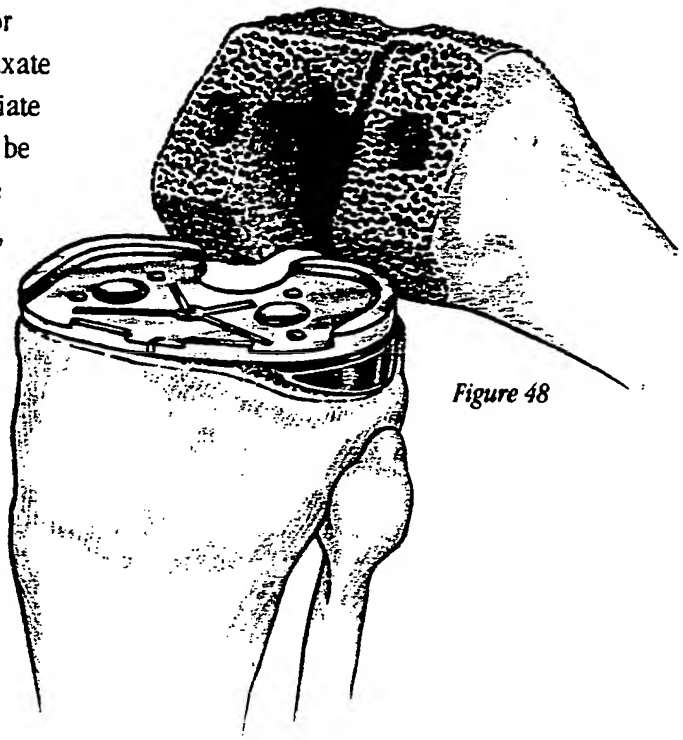


Figure 48

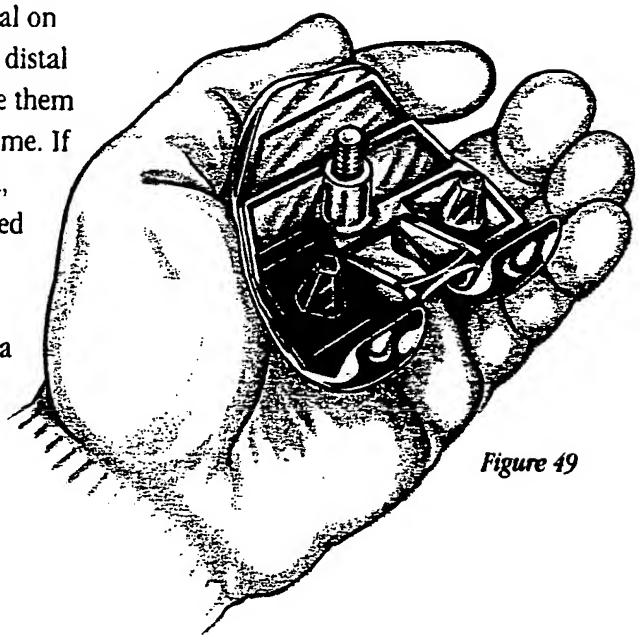


Figure 49

If posterior femoral wedges are to be used, affix these trials to the trial femoral component with bone wax. Lastly, screw the appropriately sized femoral long stem trial onto the trial conversion module *(Figure 50)*. Seat this assembly on the distal femur and impact it into position. Position the appropriate articular insert trial onto the tibial base trial. With the trial prosthesis in place, gently perform a trial range of motion to ascertain proper joint tension. Assess the rotational orientation of the tibial base.

Improper rotational orientation may result in improper femoral and/or patellar tracking. With the knee in full extension, the tibial implant should be rotationally symmetric with the femur. Check the mechanical axis of the limb using the long alignment rod. Center the proximal end of the rod on the radiographic marker over the femoral head and the distal portion on the center of the talus. The rod should pass over the center of the knee.

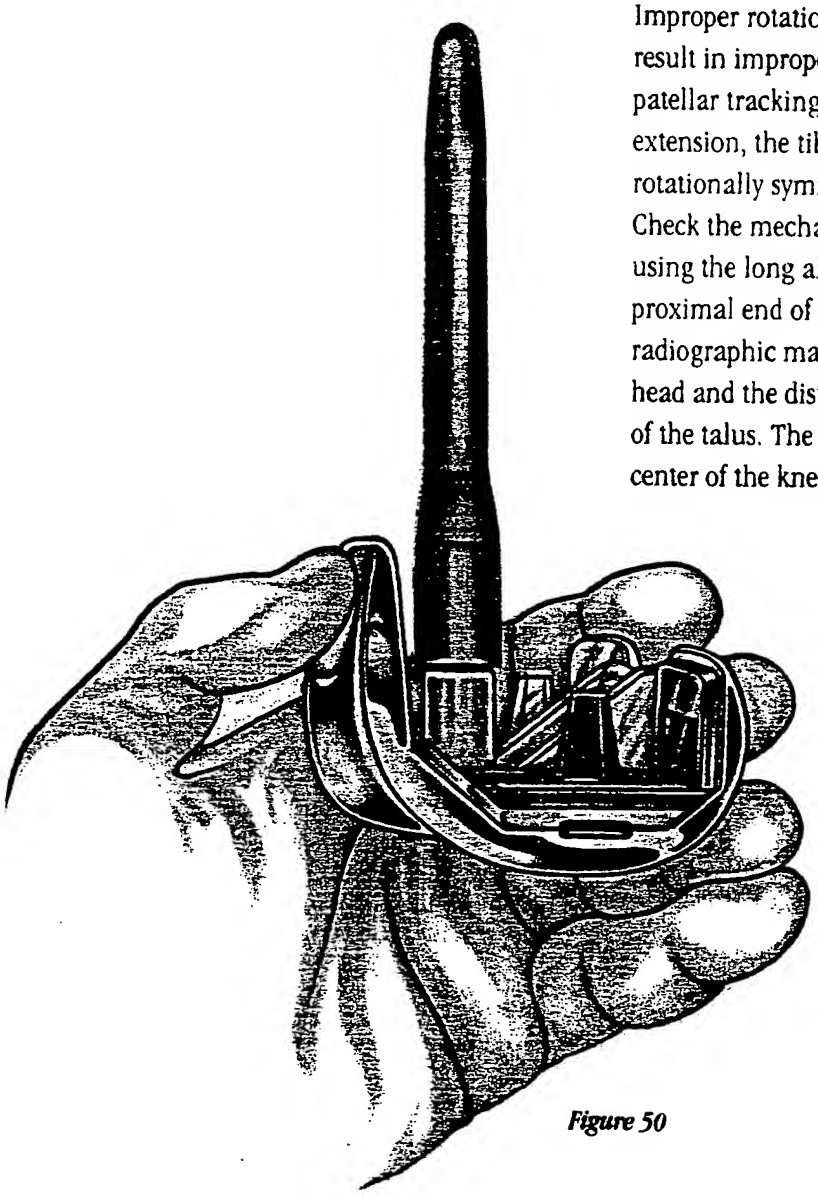
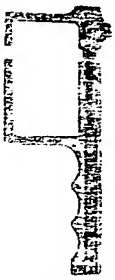


Figure 50

Patellar Reamer Guide
11-4932

Biconvex Patellar Reamer
11-4929
11-4934
11-4936



Calipers
11-4943

BICONVEX PATELLAR TECHNIQUE

The goal of revision patellar preparation is to reapproximate the height of the original or normal patella. This can be accomplished using preoperative X-rays of the affected and nonaffected knees.

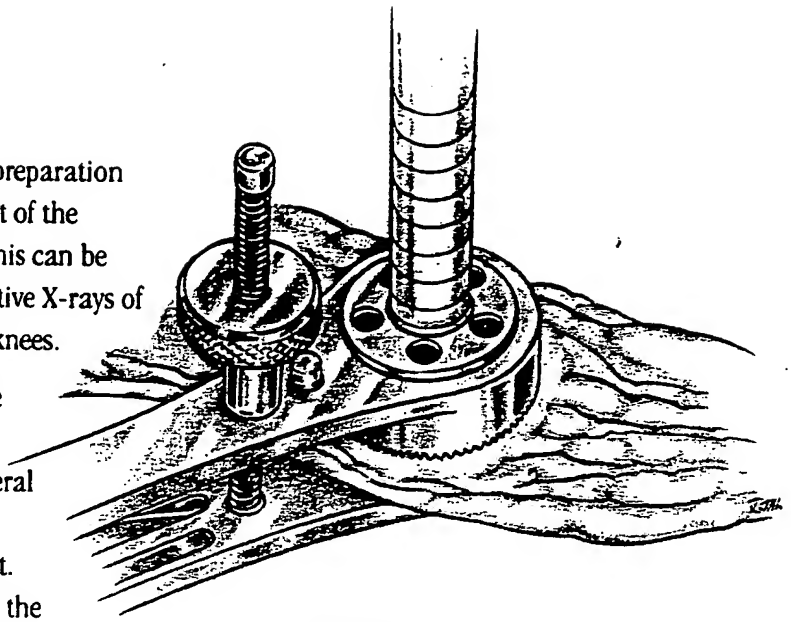


Figure 51

Extend the knee and dislocate the patella. Using a small bone rongeur, remove peripheral osteophytes. If redundant synovium is present, remove it. Make a methylene blue dot in the center of the patella. Position the patellar clamp so that the dot is in the center of the drill sleeve. Gently tighten the set screw in the clamp. In a small-boned patient, the serrated edges of the clamp will seat over the soft tissue surrounding the bone, whereas in a patient with a larger patella, the serrated edges will seat over the patella.

Insert the biconvex patellar reamer through the patellar clamp *(Figure 51)*. It should be taken into account that the biconvex patella is 13 mm (Extra-Small), 14 mm (Small), and 15 mm (Medium) thick when trying to reapproximate the original height of the patella. Ream the patella carefully. This will create a concave recess in the patella to accept the patellar implant. During this process, periodically remove the patellar drill guide, insert the trial patella, and measure the thickness with a caliper to ensure that the proper depth of reaming is attained *(Figure 52)*.

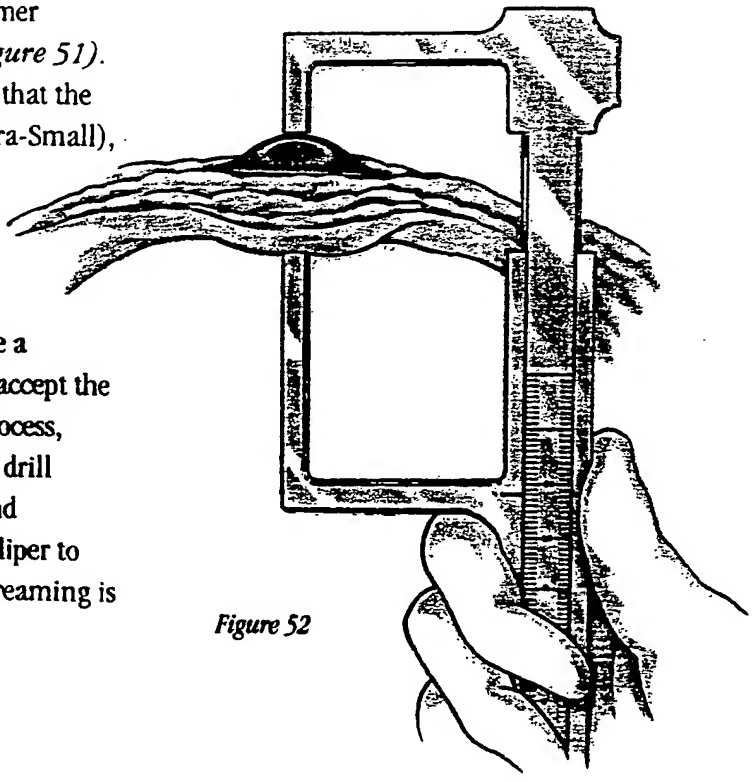
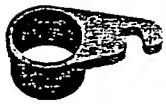


Figure 52

For the small and extra-small biconvex patellar implant, insert the small patellar reamer collet into the reamer guide and use the appropriate patellar reamer dome. Take special care if the patient is thin and osteoporotic. In deficient bone, a 70% circumferential bone rim will provide adequate stability. With such patients, less patellar bone may need to be removed to reduce the risk of fracturing the patella.



Small Patellar Reamer Collet
11-4935

After reaming is complete, place the trial biconvex patellar button in the recess to check position and depth. If necessary, use a rongeur to remove any prominent patellar surface.

Finned Cemented Punch
11-4614

KNEE PREPARATION FOR COMPONENT

After checking component tracking and knee stability through a range of motion, remove the femoral and patellar trials. Using the cemented tibial fin punch, punch through the slots in the metal tibial tray *(Figure 53)*.

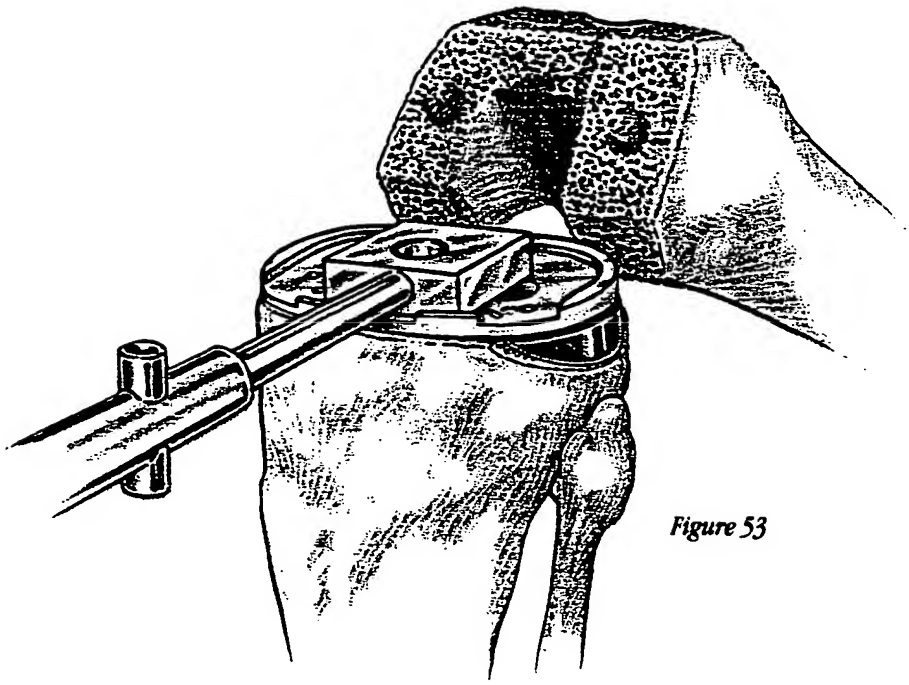
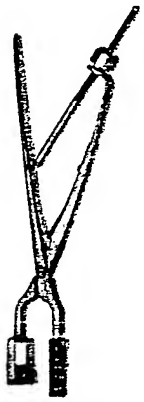


Figure 53

13 mm Tibial Punch
11-4917



Tibial Wedge Cement Clamp
11-4821

Remove the fin punch and tibial trial. If a tibial long stem is not needed and a cement mantle is preferred around the tibial peg, place the tibial drill guide on the cut surface of the tibia and secure it with two bone spikes using the previously made holes. Place a 13 mm collet into the tibial drill guide. Use the 13 mm tibial punch to enlarge the hole for the stem to provide for an even cement mantle around the peg *(Figure 54)*. Cleanse the bony surfaces by pulsatile lavage irrigation. If a tibial long stem is necessary, add it to the tibial component at this time. If any tibial wedges are to be used, cement them in place, making sure that they are placed in the same orientation as the trial wedges were placed on the trial tibial base. They may be held in the proper location by using the wedge cement clamp *(Figure 55)*. The excess cement may be used to cement the patellar component and any posterior femoral wedges used in place.

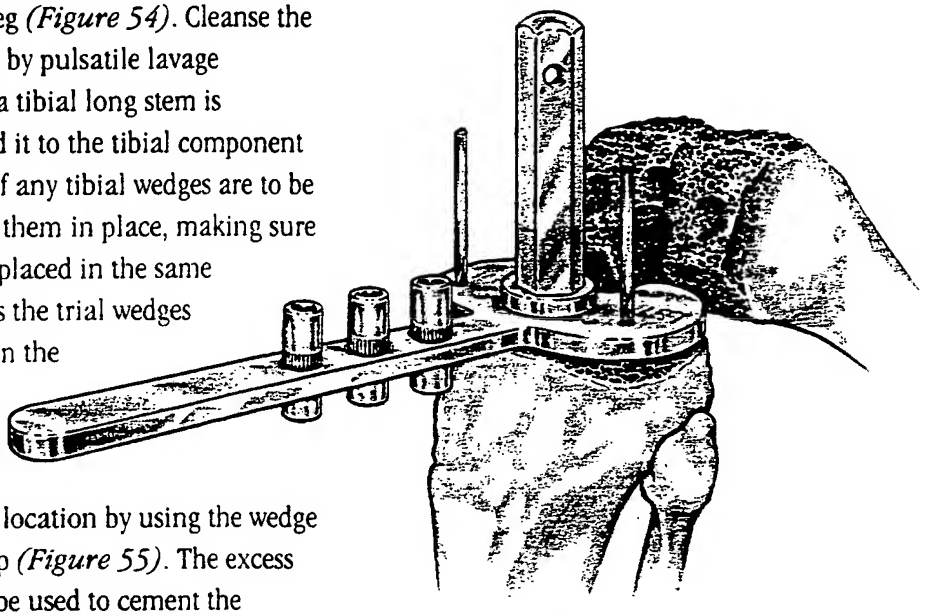


Figure 54

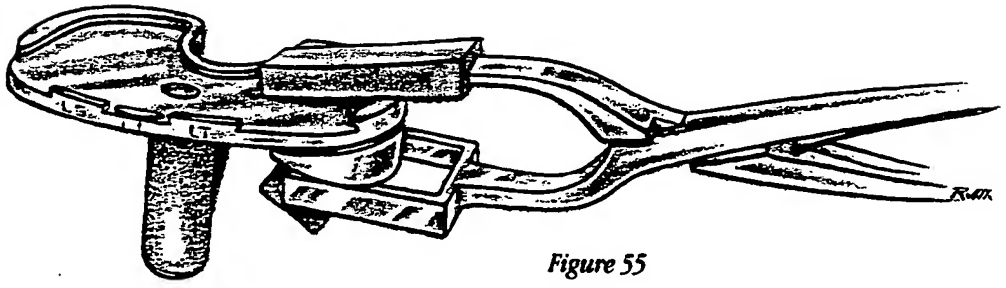


Figure 55

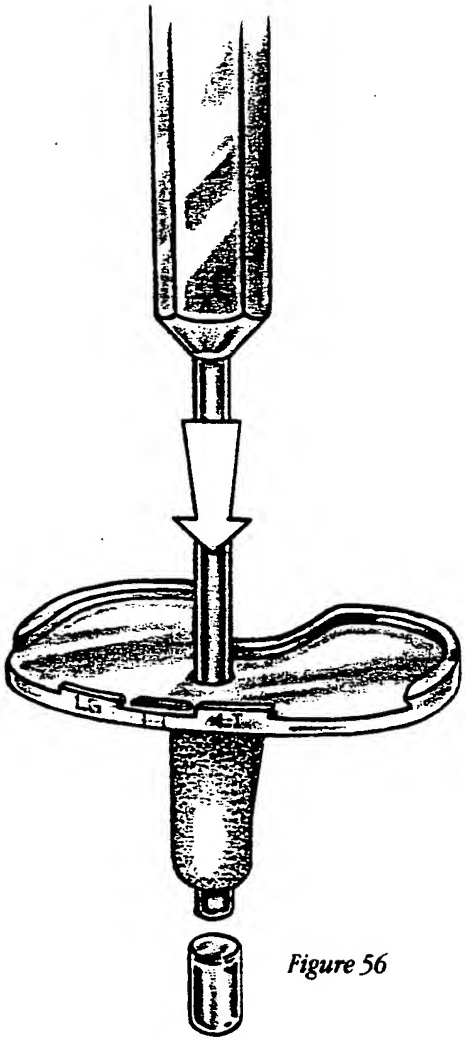


Figure 56

First, remove the metal cement plug from the distal end of the tibial component's peg by inserting the plug removal tool through the hole in the superior face of the component. A firm tap with the plug remover will dislodge the plug *(Figure 56)*. Now insert the male taper of the long stem into the female recess in the tibial component and firmly impact the distal end of the long stem to affix the two components. Subluxate the tibia forward by hyperflexing the knee, placing a hand on the posterior calf and pulling the tibia anteriorly. It is helpful to place a Hohman retractor or similar device posteriorly on the tibia to hold the tibia in an anteriorly displaced position. After the cement between the tibial base and any wedges placed has hardened, mix a package or two of acrylic cement in the cement gun. Inject cement onto the cut surface of the proximal tibia. Impact the tibial implant base plate and remove any extruded cement.

Tibial Plug Punch
11-4928

Position the previously determined femoral trial onto the femur and the trial tibial articular insert onto the base plate and extend the knee. This will ensure that full extension will be achieved once the implants are cemented and that the tibial implant is seated fully on the tibia. Do not place varus or valgus stress on the knee or hyperextend the knee which could result in uneven contact between the tibial implant and the tibia. After the tibial cement mantle has hardened, remove the tibial trial insert and femoral trial. Remove any excess cement from around the tibia and the posterior aspect of the joint.

Prepare the femur again with a pulsatile lavage. Choose the correctly sized femoral component, conversion module, wedges, and long stem. Assemble them in the same manner that the trial was assembled. If distal femoral wedges are chosen, use a Christmas tree fixation lug that is packaged sterile along with the implant wedge. If posterior femoral wedges are used, these will be cemented to the femoral component. The femoral long stem is attached to the femoral conversion module via a morse-type taper. It is important to turn the torque wrench until you feel a "break" when tightening the femoral fixation lugs in place. This will ensure that 70-inch pounds of torque has been applied to the lugs. DO NOT APPLY ACRYLIC BONE CEMENT BETWEEN THE DISTAL WEDGES, THE CONVERSION MODULE, AND THE FEMORAL COMPONENT. After the cement between the posterior wedge(s) and the femoral component has hardened, mix another package of cement. Use the cement gun to place it onto the femoral surface. Place the femoral implant onto the femur with its pegs aligned with the peg holes. Impact the femoral implant into position. Remove any excess cement. Special care should be taken to remove any excess cement within the femoral notch. Excess cement left behind in the notch could later affect the kinematics of the knee components. With the tibial trial insert in place, extend the knee to be sure the femoral implant is fully seated.

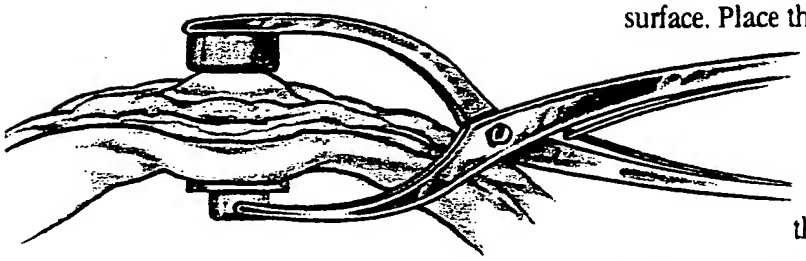


Figure 57

If the patella has not been previously cemented during wedge attachment, inject cement into the cut patellar surface. Place the patellar component in place and hold it with the patellar clamp *(Figure 57)*. Remove any extruded cement. Once the cement has hardened, remove any excess cement from the femur or patella.

Patellar Cement Clamp
11-4946

With the trial tibial articular surface in place, check the knee's stability and patellar tracking throughout a full range of motion. If patellar tracking is not satisfactory, perform the appropriate releases.

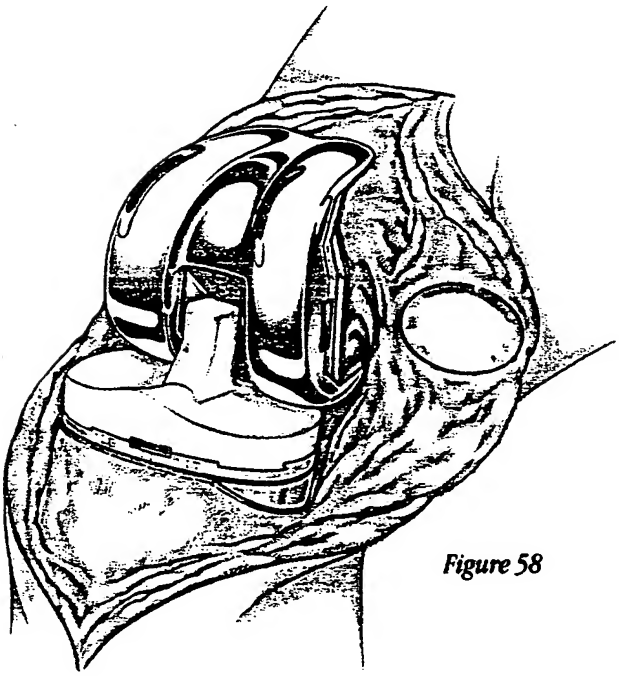


Figure 58

Once satisfactory tracking and stability have been achieved, remove the trial tibial insert and insert the polyethylene articular insert from the front *(Figure 58)*. The grooves in the polyethylene insert must engage the dovetail locking mechanism on the medial and lateral sides of the tibial tray. Ensure that the insert is fully seated. Release the tourniquet and obtain hemostasis. Clean the knee thoroughly with a pulsatile lavage. Place two large suction drains within the knee and close the knee in layers. Nonabsorbable suture is recommended for closure of the fascial layer. Once the deep portion of the closure has been completed, flex the knee to be sure that a watertight closure has been obtained.

Close the subcutaneous tissues and skin. Primary wound healing should be the goal and meticulous skin closure is essential. Place a sterile dressing followed by an elastic bandage over the wound. Obtain radiographs of the knee in both the anterior-posterior and medial-lateral projections. Continuous passive motion may be started or motion may be delayed with the knee immobilizer, depending upon the preference of the surgeon.

POSTOPERATIVE CARE

The patient's drains are removed when drainage has ceased, usually within 48 hours. Quadriceps setting exercises may be done immediately postoperatively. Once the drains are removed, the patient begins ambulating and a supervised physical therapy program for range of motion is implemented. A knee immobilizer may be used during sleeping to encourage knee extension.

The patient should use a walker or crutches until wound healing has occurred and muscle strength is recovered. This usually requires a period of six weeks. Weight bearing is performed to patient tolerance. When the patient can actively achieve full knee extension, use of the knee immobilizer can be discontinued. An outpatient program of physical therapy should continue for at least six weeks following hospital dismissal.

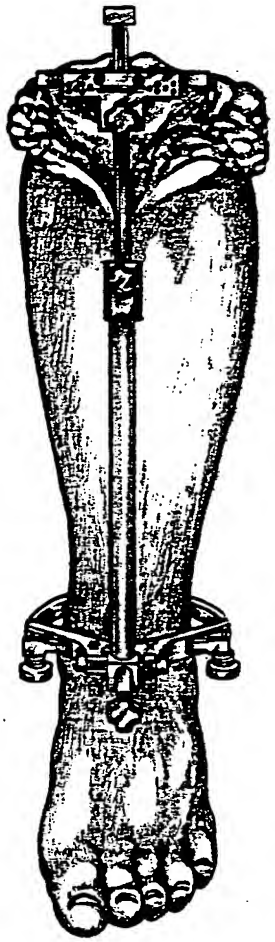


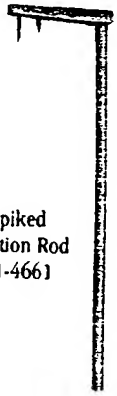
Figure 1

OPTIONAL EXTRAMEDULLARY TIBIAL ALIGNMENT TECHNIQUE

Acutely flex the knee and subluxate the tibia forward. Use a wide blade Hohman or similar blunt retractor carefully placed in the intercondylar notch to subluxate the tibia anteriorly. Be careful not to damage the distal femur especially in osteoporotic patients. Retraction should be gentle, with careful attention to the patellar ligament attachment on the tibia to prevent patellar tendon avulsion.

The surgeon has the choice between a proximally spiked fixation rod and a non-spiked proximal rod. If the proximally spiked rod is selected, slide the rod through the slotted or nonslotted tibial cutting block. If the nonspiked proximal rod is utilized, slide the chosen tibial cutting block over the top until it hits the stop. Both the slotted and nonslotted cutting blocks are available with 0° and 3° posterior sloped cut. Only 0° blocks can be used if a long stem will be needed. The rod is then inserted in the alignment sleeve which is attached to the ankle clamp. After locking the ankle clamp in the open position, place the assembly over the anterior crest of the tibia with the ankle clamp over the ankle *(Figure 1)*. The distal portion of the tibial assembly should lie over the center of the tibia which is medial to the center of the ankle. To secure the ankle clamp, depress the button on either side of the ankle clamp.

Ankle Clamp and Alignment Sleeve
11-4660



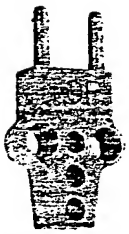
Spiked Fixation Rod
11-4661

Proximal Rod
11-4662

Tibial Cutting Block
0° – 11-4663
3° – 11-4665

Tibial Cutting Block, Slotted
0° – 11-4664
3° – 11-4666

Extramedullary
Alignment Rod
11-4861



Extramedullary
Alignment Tower
11-4667

The ankle clamp allows the surgeon to offset the distal end of the alignment guide up to 8 mm toward the medial side to allow alignment over the center of the talus. An offset of 8 mm minimizes the chance for a varus cut. Extend the proximal portion of the tibial assembly up over the proximal tibia. Impact the long spike into the proximal tibia at a point just anterior to the tibial spine. Adjust the position of the distal portion of the rod assembly until the rod is parallel to the mid-coronal plane of the tibia to ensure that the tibial cut is perpendicular to the tibial axis in all planes. The extramedullary alignment tower and rod can be used as a method of checking this alignment. (If the cutting plane is in varus or valgus, the distal 8 mm offset can be fine-tuned at this time to ensure correct alignment of the tibial cut.) If a posterior sloped cut is desired, adjust the position of the distal portion of the assembly to the desired angle (no more than 5°) or use the 3° posterior sloped cutting block. However, if a tibial long stemmed component is used, a 0° sagittal cut must be performed. Impact the shorter spike on the proximal portion of the assembly into the tibia *(Figure 2)*.

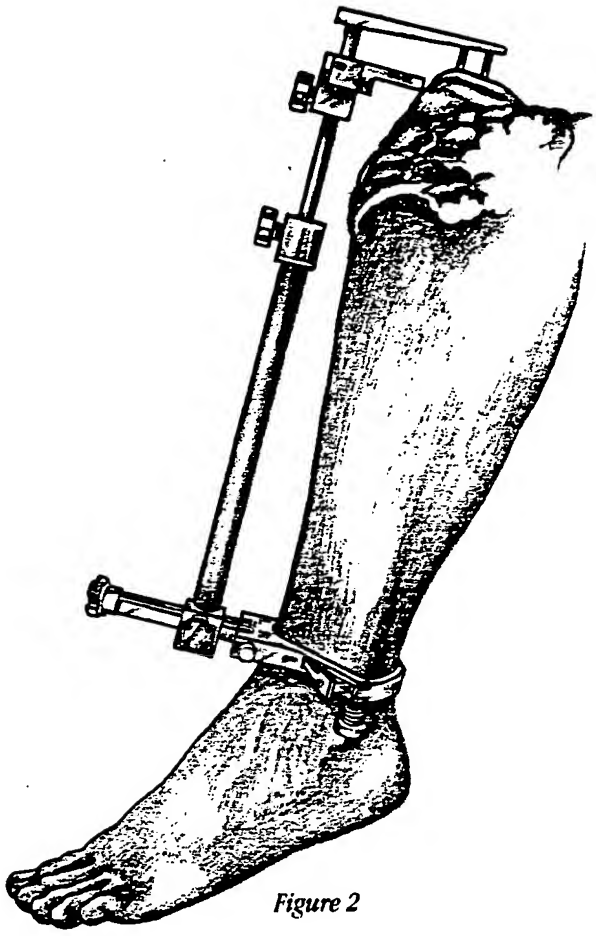


Figure 2

Assess the compartments of the tibia to determine the lowest point of the tibia. In case of large bone loss on the medial or lateral compartment, it may be necessary to adjust the cutting level proximal to or above the level of maximum bone loss and to subsequently bone graft the defect or use an augmentation wedge. Raise the tibial cutting block to its most proximal position on the extramedullary alignment rod.

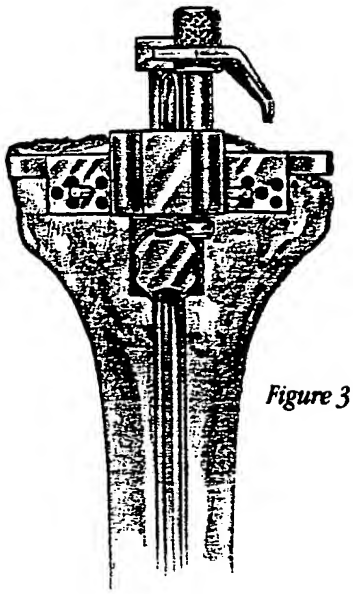
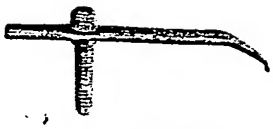


Figure 3

Attach the desired proximal tibial stylus and tighten the stylus down by its knurled knob. Five different stylus levels are available: 0, 2, 4, 6, and 8 mm. Using the 0 mm stylus, the level of cut will be even with the end of the stylus gauge. When using the 2 mm stylus, the level of cut is 2 mm below the end of the stylus gauge, and so on.



Tibial Stylus
11-4668
11-4671
11-4672
11-4673
11-4674

Position the stylus so that a minimal amount of bone will be removed from the tibia. There are two holes in the tibial block on either side of the extramedullary alignment rod. Insert a ⅛" pin into one hole on each side of the tibial rod assembly to affix the tibial cutting block to the anterior surface of the tibia *(Figure 3)*. Optional 45° angled holes on either side of the block may be used for additional stability. Take care to retract the patellar ligament laterally, so that it is not impaled by a drill.

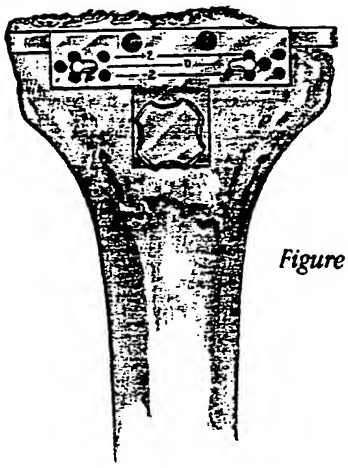


Figure 4

Once the tibial cutting block is securely affixed to the tibia, the tibial stylus and alignment assembly can be removed leaving only the tibial cutting block *(Figure 4)*. Using the anterior reference guide, carefully compare the level of the tibial cutting surface to the bone deficiency on the tibia. If it appears that too little bone is going to be removed, the block can be adjusted to remove 2 mm more bone *(Figure 5)*. If it appears that too much bone will be removed, the block can be adjusted to remove 2 mm less bone. Once the correct height of the tibial cutting block has been selected, check the orientation of the tibial cutting block in the varus-valgus plane. This can be done by attaching the extramedullary alignment tower to the

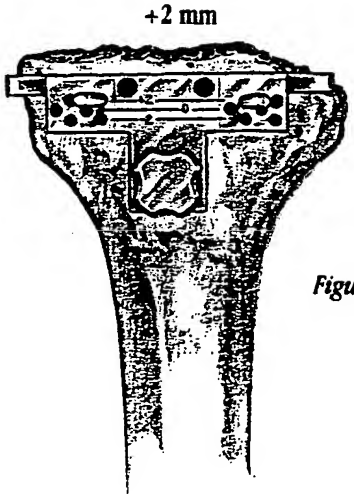


Figure 5

Wide PCL Retractor
7121-0020

tibial cutting block and placing a long extramedullary alignment rod through the tower. The rod should center on the talus in both the coronal and sagittal planes. If the orientation of the tibial cutting block is correct, the tibia is ready to be cut.

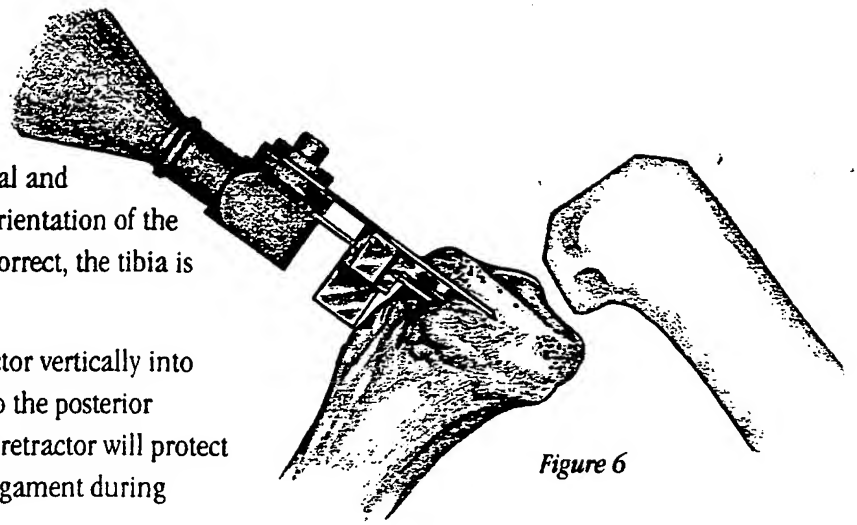
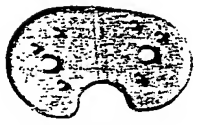


Figure 6

Place a wide PCL retractor vertically into the tibia just anterior to the posterior cruciate ligament. The retractor will protect the posterior cruciate ligament during osteotomy of the tibia.



Tibial Viewing Plate
11-4920
11-4922
11-4924
11-4926
11-4927

Using a GENESIS sawblade and an oscillating saw, resect the proximal tibia by cutting across the proximal portion of the tibial cutting block *(Figure 6)* or through the slot. Keep the sawblade flush with the tibial cutting block to ensure a flat cut. It may be necessary to remove the tibial cutting block and pins to complete the posterior portion of the cut. Using a reciprocating saw, cut a small notch posteriorly on each side of the retractor to remove the cut portion of the tibial bone. The remaining bone can be removed with a rongeur to allow seating of the tibial component. This will prevent inadvertent injury to the posterior cruciate ligament. Check the cut surface of the tibia to be sure that it is flat using a straight edge or the tibial viewing plate. Level any high spots with a saw or file. Size the tibia using the tibial viewing plate *(Figure 7)*.

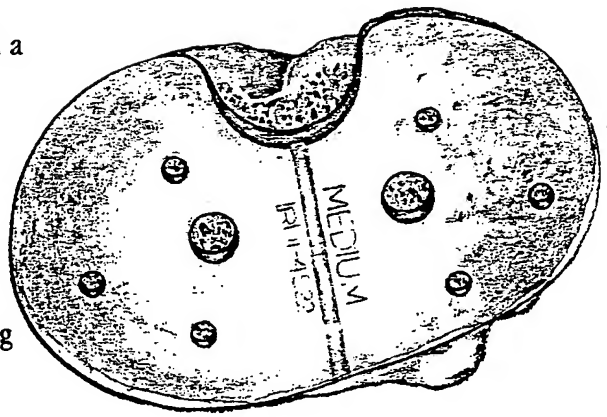


Figure 7

IMPORTANT MEDICAL INFORMATION

Warnings and Precautions

GENESIS TOTAL KNEE SYTEM

For Cemented Use Only

MATERIALS

GENESIS femoral components and femoral conversion modules are Cobalt Chromium Alloy (ASTM F 75). GENESIS tibial component bases, tibial and femoral wedges, tibial pegs, and porous patellar bases are titanium 6Al-4V alloy. GENESIS tibial component articular inserts, patellar components, and Flex-Lok pegs are ultra-high molecular weight polyethylene (ASTM F 648). Porous tibial and patellar components feature a coating of unalloyed titanium (ASTM F 67) beads. The GENESIS Total Knee System is designed as a system and DOES NOT ALLOW THE SUBSTITUTION OF COMPONENTS FROM OTHER SYSTEMS.

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

The general principles of good patient selection and sound surgical judgment apply to the total knee procedure. Preoperative planning and meticulous surgical technique are essential to achieve optimum results. Considerations of anatomic loading, soft tissue condition, and component placement are critical to minimize a variety of postoperative complications.

Indications:

1. Rheumatoid arthritis.
2. Posttraumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result.
3. Failed osteotomies or unicompartmental replacement.

Contraindications:

1. Inadequate bony support or cement support.
2. Previous intra-articular infections.
3. Mental or neurologic conditions that tend to preempt the patient's ability or willingness to restrict activities.
4. Neuropathic (Charcot) joint.
5. Conditions that tend to place increased loads on implants such as age, weight, and activity level, which are incompatible with a satisfactory long-term result.

Possible Adverse Effects:

1. Loosening, bending, cracking, or fracture of femoral, tibial, or patellar components.
2. Dislocation, subluxation, rotation phenomenon, flexion contracture, decreased range of motion, lengthening or shortening of the leg, looseness of components, or extraneous bone or ligament laxity.
3. Tibial, femoral, or patellar fractures.
4. Acute post-surgical wound infection, late deep wound sepsis, and/or low-grade synovitis.
5. Neuropathies.
6. Cardiovascular disorders: wound hematoma, thromboembolic diseases including venous thrombosis and pulmonary embolus.
7. Tissue reactions: Macrophage and foreign body reaction. Also, myositis ossificans.
8. Skin sloughs or delayed wound healing.

WARNINGS AND PRECAUTIONS

Preoperative:

1. Use care in handling and storing of implant components. Cutting, bending, or scratching the surfaces of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These in turn may induce internal stresses that are not obvious to the eye and may lead to fracture of the component.
2. Adequate inventory of implant sizes should be available at the time of surgery.

Operative:

1. Adequate and continuous support of components by cement and/or bone, and proper component size are important.
2. Proper axial and rotational alignment is important.
3. During curing of cement, care should be taken to prevent moving of the implant components.
4. Prior to closure, the surgical site should be thoroughly cleaned of bone chips, extraneous cement, ectopic bone, etc. Foreign particles at the metal-plastic interface may cause excessive wear and/or friction.

Postoperative:

1. Postoperative patient care and directions and warnings to patients by physicians are extremely important. Protected weight bearing with external support is recommended for a period of time to allow healing.
2. Use extreme care in patient handling.
3. Postoperative therapy should be structured to prevent excessive loading of the operative knee and to encourage bone healing.
4. Patients should be cautioned to limit their activities as directed by their surgeon.

Packaging and Labeling:

GENESIS implants are sterilized products and should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION

All metal components have been sterilized by a minimum of 2.5 megarads of gamma irradiation. Plastic components have been sterilized by ethylene oxide gas. All components are supplied in protective trays. Inspect packages for punctures or other damage prior to surgery.

RESTERILIZATION

Metal Components

Metal components may be resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all the original packaging and labeling. Protect prosthesis, particularly mating surfaces, from contact with metal or other hard objects.

Plastic Components

Plastic components may be resterilized by ethylene oxide gas, using the sterilizer manufacturer's instructions. Suggested aeration time is 48 hours at room temperature or eight hours at 60°C to 12 hours at 50°C with power aeration. Consult aerator manufacturer for more specific instructions.

INFORMATION

For further information, please contact Smith & Nephew Richards Inc., Customer Service Department at 1-800-238-7538.

Smith & Nephew Richards

Smith+Nephew

Leadership in Worldwide Healthcare

Smith & Nephew Richards Inc. • 1450 Brooks Road • Memphis, TN 38116 U.S.A.
(901) 396-2121 • For information: 1-800-821-5700 • For orders and order inquiries: 1-800-238-7538